EPA Jacket 35900-2 Vol.1

Decision# Submission bar	35944 CODE #	11 78263	REV	IEWER_K	9
CODING FORM FOR	<u> APPLICA</u>	TIONS FO	R REGIST	ו/אַסַבַדַּבַּםיּ	MENDMENT
FILE SYMBOL/REG NO.	35900-	2 PM	<u>33</u> ,	VETION COD	e <u>332</u>
DESCRIPTOR					• • • • • • • • • • • • • • • • • • •
[] CHILD RESIST	TANT PACKA	ging: -{ [[IDENTIAL 1	USE ONLY
REGISTRATION TYP	E: []	CONDITIONA	i j	UNCONDIT	IONAL .
PROPOSED CLASSIF	ICATION:	[] GENE	RAL []	RESTRICT	ED USE
DATE ON APPLICAT	r Ion E	PA RECEIVI	e DATE	PM RECE	:IVE 'DATE-
07 15 05		7 27		07 2	· · · · · · · · · · · · · · · · · · ·
TETHOD GF-SI	PPGRT ·	, y.	CRACENIO	LS. Exenpti	ON
(j not a	TIVE: UBMITTED PPLICABLE RECT/RESUI] NOT A	TTED SUBMITTED PPLICABLE RECT/RESU	···
VEATER (2) VERGOCOSTAN	PACK #	SENT	DATE	RETURNED	
CHEMISTRY		•		•	
EFFICACY		4	•	•	
TOXICOLOGY		• •			
HED TOX.				_	
ENVIRON. FATE		•	•		
FISH/WILDLIFE					•
OTHER:			:	•	<i>4.5</i> *
STATUS			•	-	
**************************************	•	·.	**		
FFFPONES CODE	17		SPONSE D	ATE 08//	7/05



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG 1 7 895

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Christina M. Swick Agent for, Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017

Mail to: Lewis & Harrison 122 C Street, N.W., Suite 740 Washington, D.C. 20001

Subject: HYgene

EPA Registration Number 35900-2 Your Amendment Dated July 15th, 2005 EPA Received Date July 27th, 2005

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to update the basic Confidential Statement of Formula to include an additional production facility, is acceptable.

Your notification has been made part of the permanent record for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)

LEWIS & HARRISON

122 C Street, N.W., Suite 740 Washington, D.C. 20001

Telephone 202,393,3903 fax 202,393,3906

Consultants in Government Affairs

July 15, 2005

HAND DELIVERED

Office of Pesticide Programs
Antimicrobial Division
Document Processing Desk (NOTIF)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, Virginia 22202

ATTN:

Marshall Swindell

Product Manager, Team 33

SUBJECT:

Ionics, Inc.

HYgene Bacteriostatic Water Filter Media (EPA Reg. No. 35900-2)

Notification of Revised CSF

Dear Mr. Swindell:

As agent for Ionics, Inc., I am submitting a notification to update the basic CSF for HYgene Bacteriostatic Water Filter Media (EPA Reg. No. 35900-2). The new basic CSF includes an additional production facility. Ionics, Inc. affirms that the beginning materials, manufacturing process, preliminary analyses, and other product chemistry data remain unchanged. Accordingly, the nominal concentrations, upper, and lower certified limits for the active ingredient and all impurities are identical to those which appear on the currently approved CSF.

The following documents are enclosed to support this notification:

1. Application for Pesticide Notification (OPP ID No. 296849); and,

2. Basic Confidential Statement of Formula (CSF) dated July 15, 2005.

If you have any questions and/or comments, please feel free to contact me at 202-393-3903 x16 or cswick@lewisharrison.com.

Sincerely yours,

Christina M. Swick Agent for Ionics, Inc.

Unristina M. Sinck

Enclosures

Please read instructions on revers	e before completing form.		Form Approve	d, OMB No. 2070	0060, Approval expires 05-3 t-98		
O EDA	United States		Registr	ation	OPP Identifier Number		
EPA	Environmental Protecti	on Agency	Amend		296849		
	Washington, DC 20	460		Notification	2000-10		
					<u> </u>		
	Applicat		sticide - Section	11	T. B. Dannad Classification		
t. Company/Product Number 35900-2			roduct Manager II Swindell		Proposed Classification		
4. Company/Product (Name)		PM#			None Restricted		
HYgene Bacteriostatic Water		Team 33					
 Name and Address of Applic Ionics, Inc. 	ant (include ZIP Code)				ith FIFRA Section 3(c)(3)		
3039 Washington Pike		(D)(I), m	y product is simila	ir or identical i	n composition and labeling		
Bridgeville, PA 15017		1	g. No				
PLEASE SEND ALL C	ORRESPONDENCE TO	ĺ			•••		
<u>"CONTACT POIN"</u>	T" LISTED BELOW	Product	Name		,,		
Check if this is a n	ow address		· · · · · · · · · · · · · · · · · · ·				
		Sectio	n - 11				
Amendment - Explain be	ow.		Final printed lab	els in response to	Agency letter dated		
I ==	e to Agency letter dated	······	Me Too" Applica				
Notification - Explain belo		/Co- Cootio	Other - Explain I				
Explanation: Use addit	ional page(s) if necessary.	(FOI SECTIO	a rand Section II.	,			
	Notification of Revision	of CSF in A	ccordance With P	R Notice 98-10			
					es have been made to the labeling or my false stotement to EPA. I further		
	in is not consistent with the terms of						
	subject to enforcement oct	on ond penalties	under sections 12 and .	l4 of FIFRA.			
Signature: Christian	M. Lwick		Date: 7/16	105			
		Section	n - III				
t. Material This Product Will B							
Child-Resistant Packaging Yes*	Unit Packaging Yes	İ	Water Soluble Pack	eping	2. Type of Container Metal		
No No			∏ No	-	Plastic		
	If "Yes"	No. per	II "Yes"	No. per	Glass		
*Certification must	Unit Packaging wgt.	container	Package wgt.	container	Paper		
be submitted					Other.		
3. Location of Net Contents In		Retail Containe	er		Label Directions		
Label	Containe/			On Label			
6. Manner in Which Label is A	ffixed to Product Lithog	ranh	Other	Un labeli	ng accompanying product		
o. manifest (() 11mg/1 2000 (10)	Peper		£ Oliioi				
	☐ Stenci						
		Section	1 - IV				
Contact Point (Complete iter	ns directly below for identification		o be contected, if nece				
Name Charinting M. Coviels Toronic S	P. Marrison	-	vont for toning Ind	1	Felephone No. (Include Area Code)		
Christina M. Swick, Lewis & 122 C Street NW #740, Was	3	Α	gent for Ionies, Inc	•	202-393-3903 (ext. 16)		
	Certificati	on			6. Date Application		
	ave made on this form and all att				Received		
acknowledge that any knowing under applicable law.	ly laise or misleading statement	nay ee punish:	BOIG BY TIME OF IMPRISO	mont or pote	(Stamped)		
2. Signature		3. Title			" '' ''!!!		
ChristinaM	Lunce	İ	Agent for Ionics, Ir	1c.	'''		
4. Typed Name		5. Oate			• ••••••		
Christina M. Swick, I	Lewis & Harrison		July 15, 2005		••••		

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

Please read instructions	on reverse before completin	g form.	Form /	\pproved.	OMB No. 2070	-0060		
United States				Registrat			OPP Identifier Number	
SEPA	Environmental F Westing	Amendm Other		Amendme Other	int	296849		
	A	pplication for	Pesticide - S	ection	i			*****
1. Company/Product Nu	imbe;		2. EPA Product	Manager		3. Pro	posed Classification	
4. Company/Product (N	amei		PM#]니	None Restrict	•d
	f Applicant <i>(Include ZIP Code</i>	<i>,</i>	(b)(i), my produ to:	ıct is sim		i in con	FIFRA Section 3(c)(3 apposition and labeling	
Check i	f this is a new address		Product Nan	10				
		Sec	tion - II					
Amendment - E			Agenc)	letter det		·		
Notification - Ex	response te Agenoy lettor da plain below,	(180 <u></u>	<u></u>	o" Applica Explain be				
		Sec	tion - III					
1. Material This Produc					T			
Child-Resistant Package Yes* Ne * Cartification mus	Yes No	No. per If "Ye				nteiner Aetal Testic Hass Paper Other (Sp	nacitul	
submitted	Olit Chokagang Wgt.	OO,KEINO.		<u></u>	· — ·	- CHEC (3)	3001173	
3. Locetion of Net Cont	ents Information 4. Container	Sizejoj Reteil Conta	nor	5. Lo	cetion of Label I On Label On Labeling		senying product	
8. Manner in Which Lab	sel le Affixed to Product	Lithograph Paper glued Stenciled		ther				1000
			ion - IV					
1. Contest Point (Com	plete items directly below for	identification of indiv	idual to be contac	ted, if nec	essary, to proce	es this i	pplication.)	
Name		Title		,	Te	iephone	No. linclude Arae Cod	e)
	etatemente i have made on th at eny knowingly false or mis able law.						6. Deta Application Received a. (Stamped)	-
2. Signature		3. Titie					••••	•
4. Typed Name		5, Date	-				****	

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to sverage 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, atc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.\$1 (b) (4)[:
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Examption Statement (EPA Form 8570-27);
- s. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mackup of the proposed label, if prepared for mackup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Date - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please used the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section i, iii, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, atc., Sections i, ii, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- t. Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been essigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Menager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- A. Product Name Enter the complete product name of this pesticids as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brend name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of enother party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registrated with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purposals) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual backets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Not Contents Indicate the location of the net contents information for your product.
- 4. Size of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Mapper in which imports affixed to product indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, reschaping agent, "me-top," reregistration, atc.

- 1-5. Self-expleneto*A •
- 6. EPA Usa Only

DECISION PAGEN	10. <u>70 660 de</u>	SUBM. DUE	DATE 07-11-05	-
•	CODE # 77785	•		
CODING FORM F	OR APPLICATION	NS FOR REGIST	'RATION/AMEN	DMENTS
FILE SYMBOL/REG NO	35900-2 PM_	3-3 action cod	E <u>345</u>	
DESCRIPTOR For m.	ula Change	FQPA_	NFQPA	-
[] CHILD RESIST	PANT PACKAGING:	[] REQUIRED	[] NOT REQUIRE	5
REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL	[] RESTRICTE	D DEE
DATE ON APPLICAT	TION EPA RECI	EIVE DATE	PM RECEIVE DATE	
04121.10	15 0412	2105	0412810.	. ٽ
	•		<u> </u>	
	SUPPORT	•	**	•
[] CITE-ALL [[] NOT SUBMITTED [] SELECTIVE] N/A	[] SUBMITTED [] B/A	NOT SURMITTE	D
REVIEW(S) REQUESTED		ATE DUB	DATE RETURNED	•
CHEMISTRY		ĬĮ.	14	
EFFICACY) [
		11	-	, ,
		11		
ACUTE TOX.] [
RASSB TOX ENVIRON. FATE			1 (
RASSB TOX ENVIRON. FATE] [] [] [1 (
RASSB TOX ENVIRON. FATE PISH/WILDLIPE] [] [] [] [
ACUTE TOX RASSB TOX ENVIRON. FATE PISH/WILDLIFE OTHER:] [] [] [] [

JUL 0 5 2005

Lewis & Harrison, Agent for lonics, Inc.
122 C Street NW, Suite 740
Washington, DC 20001

Attention:

Christina M. Swick

Subject:

HYgiene Bacteriostatic Water Filter Media

EPA Registration No. 35900-2

Amendment Application Date: April 21, 2005

EPA Received Date: April 22, 2005

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, to add alternate sources of inert ingredient is acceptable.

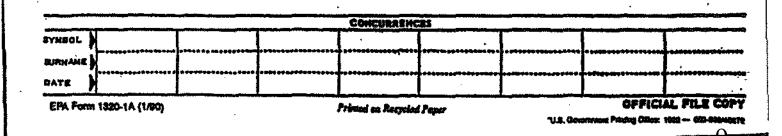
The revised alternate Confidential Statement of Formula (CSF) dated April 22, 2005, is acceptable. It is in compliance with 40 CFR, Part 158.175 and PR Notice 91-2, it agrees with the label. This information has been placed in the subject product file.

If you have any questions concerning this letter, please contact me at 703-308-6341 or Portia Jenkins at (703) 308-6230.

Sincerely yours,

Marshall Swindell Product Manager (33)

Regulatory Management Branch I Antimicrobials Division (7510C)





Please read instructions on reversa be	Form Approved, OMB No. 2070-0050, Approval expires 05-31-98					
	ì	☐ Regis	tration	OPP Identifier Number		
EPA En	vironmental Protectio	n Agency	⊠ Amen	dment	296986	
	Washington, DC 204	60	☐ Other			
	Application	n for Pesticid				
1. Company/Product Number		2. EPA Product N			3. Proposed Classification	
35900-2		Marshall Swin	deli			
4. Company/Product (Name) HYgene Bacteriostatic Water Filte		PM# Team 33			None Restrict	
5. Name and Address of Applicant (fi	nclude ZIP Code)				with FIFRA Section 3(c)(3)	
Ionics, Inc. 3039 Washington Pike		(b)(i), my prod to:	uct is simil	ar or identical	it in composition and labeling	
Bridgeville, PA 15017		EPA Reg. No.				
PLEASE SEND ALL COR				· · · · · · · · · · · · · · · · · · ·		
<u>"CONTACT POINT" I</u>	LISTED BELOW	Product Name	e			
Check if this is a new a	address	<u>) </u>		·		
		Section - II				
Amendment – Explain below.			-		e to Agency letter dated	
Resubmission in response to	Agency letter dated		le Too" Appl			
Notification - Explain below. Explanation: Use additional particles.	anale) if nacasanani (E))the: - Explai			
Explanation: Use additional p	page(s) if necessary. (F	or section rand	Section II.)	l		
i n	Minor Formul	ation Am	on d'm e	ent to ad	4.4	
ļ .	ATIMOL T. OLIMAN	ation Am	CHUIII	the to ac	uu	
***************************************	Additional So	urcas of In	nart Ir	aradiar	at	
†	Auditional So	ui ces oi ii	1161 € 11	igi culci	ut	
						
		Section - III				
1. Material This Product Will Be Pack						
Child-Resistant Packaging	Unit Packaging		Soluble Pack	aging	2. Type of Container	
│	│				Metal	
		O. per If "Yes" No. per Glass				
*Certification must	Unit Packaging wgt. cor	ntainer Package wot container			Paper	
be submitted		\$	1		Other (Specify)	
3. Location of Net Contents Information	on 4. Size(s) Reta	il Container		f Location o	of Label Directions	
I	ntainer 4, Size(s) New	in Container		5. Location o		
	,			1 =	beling accompanying product	
6. Manner in Which Label is Affixed to	= -		Other_	, ,		
	☐ Paperg ☐ Stencile					
<u> </u>		Section – IV				
A Donatora Donatora do Contra de la como	line with a banks of the state		and a second second		and the second control	
Contact Point (Complete items d		of individual to be co. Title	ntected, if he	cessary, to proc		
Name Christina M. Swick, Lewis & H	ì		for Ionics,	Inc.	Telephone No. (Include A/ea Cod 202-393-3903 x16	
122 C Street NW Suite 740, Wa					••••	
	Certificatio				6. Date Application	
I certify that the statements I have a acknowledge that any knowingly fall						
under applicable law			we or unbig	reminding of Dotti	(Stamped)	
2. Signature	3. T					
Christina M. Dur	cle	Agent f	or Ionics, l	inc.		
4. Typed Name	5. D	ate	<u> </u>	•		
Christina M. Swick, Lewis & H						
, , , ,	arrison	Apr	it 2 t, 2005	•	•	

Please read instructions	en reverse before comple	ting form.			Form Appr	oved,	OMB No. 2	070-0060	<u> </u>	
		inited States		Registra					entifier Number	
⊕EPA	Environmental Protection Ager Washington, DC 20460			ency					ont 296986	
		Applicatio	n for	Pestici	de - Sect	lion	1			
1. Company/Product Num	nber			2. EPA	roduct Mary	ger		3. P:	repeated C	lassification
4. Company/Product (Na	ne)			PM#					None	Rostricted
5. Name and Address of Applicant (Include ZIP Code)				6. Expedited Review. (n accordance with F(FRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No.						
	this is a new eddress		<u> </u>		ct Name _					
			560	tion -	<u> </u>					
Amendment - Exp	lsin below. osponse to Agency lettor	dated		_	Final printed Agency lette "Me Too" A	er date		to .		
Notification - Expl					Other - Expl					
			Sec	tion - II	İ					
1. Meterial This Product	Will Be Packaged in:		· · · · · · · · · · · · · · · · · · ·	······		******				
Child-Resistent Peckaging	Unit Packaging		Water	Soluble P	eckeging		2. Type of	Container		
Yee*	Yes			Yes				Metal Plastic		
L No	No		1 1 NA 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			Gless				
Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	li "Ye Poska	Yes" No. per Paper Other (Specify)						
3. Location of Net Conte	nte information	4. Size(s) Reta	il Conte	iner	<u> </u>	5. Loc	otion of Lab		one	
Label	Container					<u></u>	On Label On Label		npanying p	product
6. Manner in Which Labe	le Affixed to Product	Lithogr Paper o Stencile	eph lued ed		Other					
			Sect	tion - I	<u> </u>					
1. Contoct Point Comple	ete items directly below f	or identification	of indiv	ridual to be	contacted, i	f nece	ssary, to pr	oc ess this	epplication	on.)
Namo		*	Title					Telephon	e No. (Inc	lude Areo Code)
Certification is certify that the statements is have made on this form and all asknowledge that any knowingly felse or mislaading statements both under applicable law. 2. Signature 3.							nenwosing		Potr	Application ved tamped)
4. Typed Name 5. De								:		•

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per responses, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Weshington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exampted by 40 CFR 152.81 (b) (4)]:
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 8. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or o mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch fils. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Black A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, ato., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION | - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been sesigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brend name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Raylew FIFRA section 3 (a) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product [Amendment], for a resubmission in response to an Agency lotter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for ony other action that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purposets) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

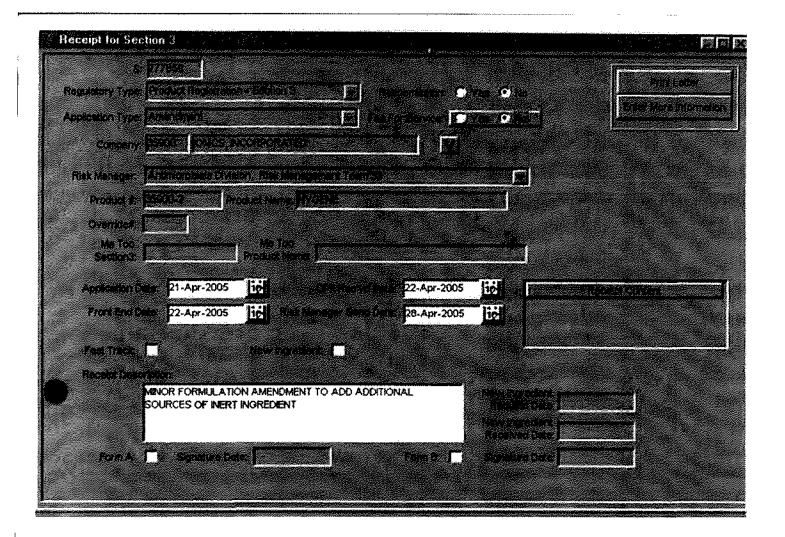
SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

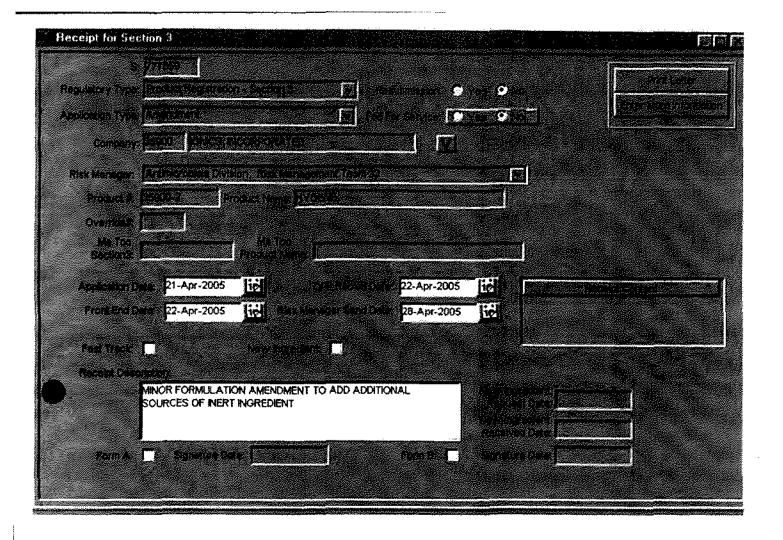
- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types, indicate the site of the indicated package and number per retail container.
- 2. Type of Retail Conteiner Indicate type of container in which product will be marketed.
- 3. Location of Mat Dentents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Consciner Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions -ingletty the location of the use directions for your product.
- 5. Manner in which label is efficed to product Indicated the method product label is attached to retail container.

SECTION (V (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "matter," aregistration atc.

- 1-5. Self-explanatory.
- 6. EPA Use Only ...

13







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 28, 2005

OFFICE OF PREVENTION, PESTICIOES AND TOXIC SUBSTANCES

CHRISTINA M. SWICK LEWIS & HARRISON, AGENT FOR IONICS, INCORPORATED 122 C STREET N.W., SUITE 740 WASHINGTON, D.C. 20001

PRODUCT NAME: HYGENE

COMPANY NAME: IONICS, INCORPORATED OPP IDENTIFICATION NUMBER: 296986

EPA FILE SYMBOL: 35900-2

EPA RECEIPT DATE: 04/22/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

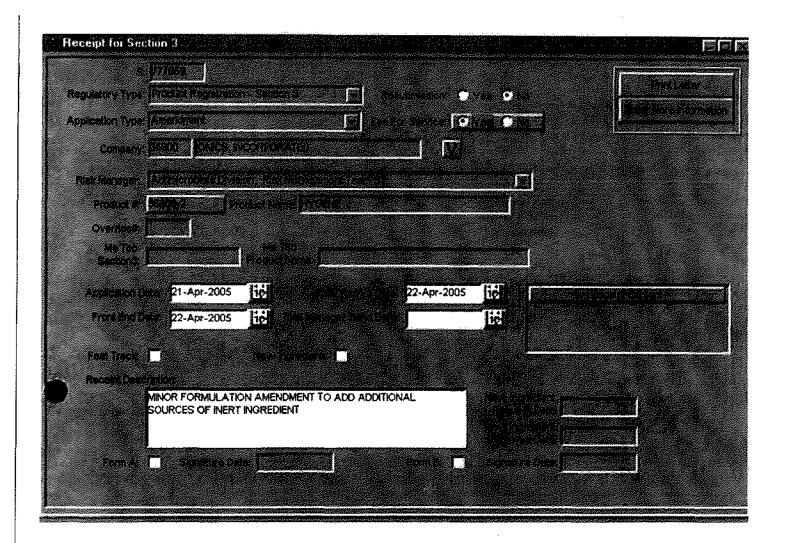
If you have any questions, please contact Antimicrobials Division, Risk Management Team 33, at (703) 308-6341.

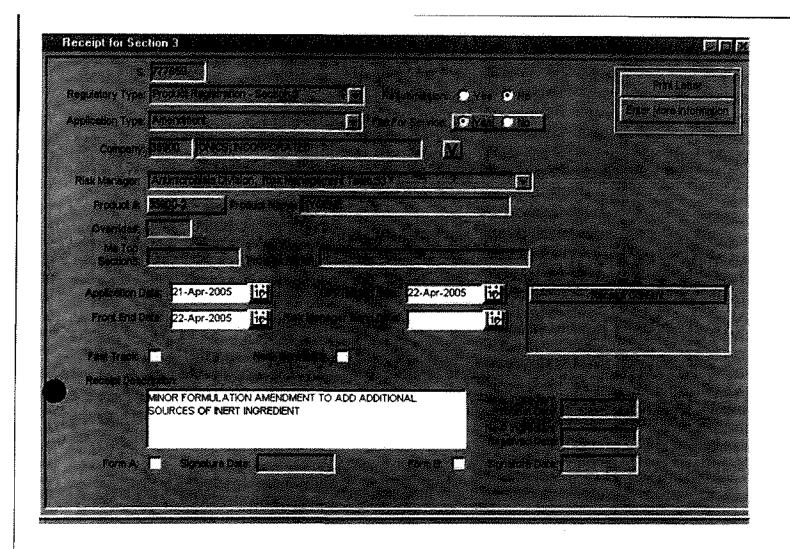
Sincerely,

Front End Processing Staff

Information Services Branch

Information Resources and Services Division





Fee for Service

This package includes the following	for Division						
☐ New Registration	□ RD						
☑ Amendment	₽ AD						
☐ Waiver Request and type	□ BPPD						
☐ 100% ☐ 50% ☐ IR-4 ☐ Minor ☐ Fed/state	Risk Mgr. <u>ま</u> 多						
Receipt Nos. S- 777859							
EPA File Symbol/Reg. No. 357	700-2						
Pin-Punch Date: 4-22	-05						
☑ This item is NOT subject to FFS action	١.						
Action Code: Requested: Granted: Amount due: \$	rent/Child Decisions:						
☐ Voluntary Payment Request	% Reduction						
Reviewer: Klean / Fish	Date: <u>4/25/05</u>						
Remarks: (use back if needed)							

DECISION PKG. NO.	356602	SUBM. DUE	DATE July 21-200	15
SUBMISSION BAR COL	DE #777 855	REVIEWER_	P. Jenkins	
CODING FORM FOR	CAPPLICATION	ONS FOR REGIS	TRATION/AMENDMENT	<u> </u>
FILE SYMBOL/REG NO. 35	7900 3 3 PM	33 ACTION CO	DS_345	
DESCRIPTOR		FQPA_	NFQPA	
() CHILD RESISTANT REGISTRATION TYPE: [[] NOT REQUIRED	
		RECEIVE DATE		
04/2/10	5 04	122105	04,28,05	
METHOD OF S [] CITE-ALL [[] NOT SUBMITTED [] SELECTIVE	FORMULATORS EXE		
REVIEW(S) REQUESTED	DATA PACK #	DATE DUE SENT DATE	DATE RETURNED	
CHEMISTRY				
EFFICACY	}} [1 [
ACUTE TOX	}} {	1 [
RASSB TOX) (1	1 I	
ENVIRON. FATE] (1[_1 (•
FISH/WILDLIFE	} (] [
OTHER::] [] İ		
STATUS				

RESPONSE CO	DDB	response	DATE	

Decision #: 356602

DATA PACKAGE BEAN SHEET

Date: 02-May-2005 Page 1 of 1

* * * Registration Information * * *

Registration:	35900-2 - HYGENE			
Company:	35900 - IONICS, INC	ORPORATED		
Risk Manager:	RM 33 - Marshall Sw	rindell - (703) 308-6341 Room# (M-2 308H	
Risk Manager Reviewer:	Portia Jenkins PJEN	KINS	eriffet annesliggeri annes annes gyragoliffe annes anne	
Sent Date:		Calculated Due Date	21-Jul-2005	Edited Due Date:
Type of Registration:	Product Registration	- Section 3		
Action Desc:	(345) FORMULA CH	ANGE;TECHNICAL;		
Ingredients:	072501, Silver(1.053	6)		
	#	* * Data Package Inf		*
Expedits:	O Yes 🌘 No	Date Sent	: 02-May-2005	Due Back:
DP Ingredient:	072501, Silver			was the second of the second o
DP Title:				
CSF included:	O Yes \varTheta No	Label Included: 🔵 Yes 🌘	No Parent	DP#:
Assigned T	<u>o_</u>	Date In	Date Out	
Organization: AD / P	PSB	5/24/05		Administrative Due Date: 16-Jun-2005
Team Name: CTT		5/24/05	, per symment, and refer to the control of the cont	Negotiated Due Date: 6/02//05
viewer Name:	606T	5/26/0		Projected Completion Date: 6/7/05
Contractor Name:				7 7

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product Chemistry Review
Action Code 345
S. No. 777865, D. No. 356602
Adm Due Date 07-21-05, Sci Due Date 06-21-05
Please review and determine if the Information submitted is acceptable of add source of inert ingredient.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES Antimicrobials Division

June 8, 2005

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Hygene

DP Barcode: D316506

Reg. No. Or File Symbol: 35900-2

Manufacturing-use [] OR

End-use Product [X]

TO:

Marshall Swindell PM 33 / Portia Jenkins, Team Reviewer

Regulatory Management Branch I Antimicrobials Division (7510C)

FROM:

Robert Turpin, Chemist

Product Science Branch, CT Team

Antimicrobials Division (7510C)

THRU:

Karen P. Hicks, CT Team Leader

Product Science Branch

Antimicrobials Division (7510C)

THRU:

Michele E. Wingfield, Chief

Product Science Branch

Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)

% by wt.

BACKGROUND: The registrant has submitted an amendment to add alternate sources of the inert ingredient to the Confidential Statement of Formula (CSF) of the subject product. In support of the amendment, the registrant has submitted technical data and Material Safety Data Sheets of each of the alternate products.

FINDINGS:

The alternate sources of the inert ingredient, activated carbon, are acceptable.

RECOMMENDATIONS: None.

31910-2

9 28/2000



a division of National Starch and Chemical Company

909 Mueller Drive PO Box 5401 Chattanooga, TN 37406 Phone: 423-629-1405 Fax 423-698-8723

Technical Information

Polymers and Microbiocides for Industrial Water Treating

AQUATREAT®

TB 5066 7/21/00

ACCEPTED

SEP 2 8 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 2/9/0 - &

AQUATREAT® DNM-30

EPA REG, NO. 31910-2

ADDITIONAL USE PATTERN #1:

SEAWATER COOLING TREATMENT (for marine use only)

AQUATREAT® DNM-30 is a highly effective antifoulant and seawater biocide designed to control the growth of microorganisms (bacteria and fungi) and barnacle larvae on shipboard seawater heat exchangers.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This product must not be used on any food or field crop or to formulate any product for use on any food or field crop.

To achieve best control of Fouling, AQUATREAT DNM-30 or seawater cooling treatment should be applied to a clean system. If fouling is present, it is recommended that the system be thoroughly cleaned prior to its use.

For best results, treat the system with 10 ppm of AQUATREAT DNM-30 for 100 minutes every 3-4 days. To treat at 10 ppm, feed at the rate of 3.88 pounds per 100 tons/hr. (50.72 fl. oz. or 1.5 liters per 100 tons/hr.) of system flow rate. The frequency of dosing may be less, depending on the degree of fouling.

AQUATREAT DNM-30 is completely soluble in seawater and can be conveniently fed directly from the drum or from a dosing tank. The best point of feed is as early as possible in the system, preferably before any strainer or heat transfer surfaces. The most common point is to dose the sea chest.



The eformation given and the recommendations made herein are based on our research and are believed to be accounted but no gueranty of their accountry is made. In every case, we urge and recommend that purchasers, before using any product in full scale production, make their own tests to determine to their own special description of acceptable quality and is suitable for their particular purposes under their own operating conditions. THE PRODUCTS DISCUSSED HEREIN ARE 50,0 WITHOUT ANY WARRANTY AS TO MERCHANTABETTY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESSED OR SIPLETO, No representative of ours has any authority to well or thange the foreign provisions but, excited to such provisions, our engineers are evel-table to asset purchased and so that needs and to the organizations or the products to their needs and to the organization or any calcular patients or to constitute a

24

276

PAGE 2 ADDITIONAL USE PATTERN #1 AQUATREAT DNM-30 EPA REG. NO. 31910-2

AQUATREAT DNM-30 should not be fed to a system while the seawater is being drawn as makeup for an evaporator or water maker. Either is glate the evaporator or shut it down while AQUATREAT DNM-30 is being dosed and for at least 30 minutes afterwards.

TYPICAL PROPERTIES

ACTIVE INGREDIENTS:

Sodium Dimethyldithiocarbamate
Nabam (Disodium ethylene bis-dithiocarbamate
INERT INGREDIENTS

15% SEP 2 8 2000

70% 100% Under the Federal Insecticide, Funglicide, and Foderaticide Act as amended, for the pesticide, registered under EPA Reg. No. 3/4/0 - 2

ACCEPTED

APPEARANCE

TOTAL

AQUATREAT DNM-30 is a clear, yellow-green liquid with a density of 1.175 grams/cc at 20°C (9.8 lbs./gal.) and has a characteristic sulfur odor.

pH is 10.5-12.4, and the product is completely soluble in all proportions in both fresh and seawater.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. All industrial workers applying this product must wear coveralls over a long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During dilution, a chemical-resistant apron and goggles or face shield must also be worn. Harmful if swallowed. Avoid contamination of food and feedstuffs.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not apply (or use) in estuarine oil fields where drilling fluids (muds) are discharged in the surface water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PAGE 3 ADDITIONAL USE PATTERN #1 AQUATREAT® DNM-30 EPA REG. NO. 31910-2

STORAGE AND DISPOSAL

- 1. PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.
- 2. PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

- (a) Reseal container and offer for reconditioning, or
- (b) Metal Containers: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other approved state and local procedures.

Plastic Containers: Triple rinse or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed, by state and local authorities, by burning. If burned, stay out of smoke.

4. GENERAL: Consult federal, state, or local disposal authorities for approved alternative procedures.

FIRST AID

•Hold eye open and rinse slowly and gently with water for 15-20 minutes.

•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING

- Take off contaminated clothing.
- •Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED

- •Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- •Do not induce vomiting unless told to do so by the poison control center or doctor.
- •Do not give anything by mouth to an unconscious person.

IF INHALED

- •Move person to fresh air.
- •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- •Call a poison control center or doctor for further treatment advice.

ACCEPTED

SEP 2 8 2000

Under the Federal Insecticide, Fundade, and Rode nocide Act as amended, for the persocide, registered under EFA Reg. No. 3/9/0-2

PRECAUTIONARY STATEMENTS. Hazards to Humans and Domestic Animals WARNING

Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. All industrial workers applying this product must wear coverells over a long-sleeved shirt and long pants, shoes, socks, and chemical-resistant gloves. During dilution, a chemical-resistant apron and goggles or face shield must also be worn. Harmful if swallowed. Avoid contamination of food and feedstuffs.

ENVIRONMENTAL HAZARDS

This pasticide is toxic to fish. Do not apply (or use) in estuerine oil lields where dritting fluids (muds) are discharged in the surface water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless In accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

AQUATHEAT DNM-30 is a highly effective bactericide and fungicide for use in controlling the growth of bacteria and lungifound in paper mills, drilling fluids, secondary and tertiary petroteum recovery, tracturing fluids, workover and completion fluids, flue gas desulturization thickeners, hydrocarbon fluids storage, beet sugar mills, and cane sugar mills.

AQUATREAT DNM-30, in addition to being a bactericide and fungicide, is a highly effective algaecide for use in controlling the growth of algae, as well as bacteria and fungi found in industrial recirculating water cooling towers, evaporative condensors, and air washers.

STORAGE AND DISPOSAL

1. PROHIBITIONS

Do not contaminate water, lood, or leed by storage or disposal. Open dumping is prohibited.

2. PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pasticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to tabel instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the neares! EPA Regional Office for guidance.

3. CONTAINER DISPOSAL

- (a) Reseal container and offer for reconditioning, or
- (b) Metal Containers: Triple rinsa (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of In a sanitary tandfill or by other approved state and local procedures,

Ptestic Containers: Triple tinsa (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary tandfill, or incineration, or, if allowed by state and locat authorities, by burning. If burned, stay out of smoke.

4. GENERAL

Consult federal, state or local disposal authorities for approved alternative procedures.

AQUATREAT® DNM-30

AÇTİVE INGREDIENTS	
Godium Dimethyldithiocarbamate	15%
Nabam (Disodium Ethylene	
Bis-dithiocarbamate)	1596
INERT INGREDIENTS	70%
TOTAL	10096

KEEF	OUT OF REACH OF CHILDREN
	WARNING
	FIRST AID
IF IN EVES	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact tenses, if present, after the first 3 minutes, then continue rinsing eye.
	Call a poison control center or doctor for treatment advisor.
IF ON SKIN OR	Take off contaminated clothing.
CLOTHING	Rinze (kin immediately with plenty of water for 15-20 minutes.
	. Call a poison control censer or doctor for treatment advice.
IF SWALLOWED	Call a poison control ceater or doctor immediately for treatment advice.
	" Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to do so by the poison control center or doctor.
	Do not give anything by mouth to an unconscious person.
IF INHALED	Move person to fresh sir.
	If person is not breathing, call 911 or an ambulance, those give artificial respiration, preferably by mouth-to-mouth, if possible.
	Call's poison control centes or doctor for furthes treatment advice.
	HOT LINE NUMBER

Have the product containes as label with you when calling a posson control center or doctor, or going for treatment. You may also call 1 \$55 (56-621) day or alghr for emergency medical treatment information

> See Side Panel For Additional Precautionary Statements.

ACCEPTED

SEP 2 8 2000

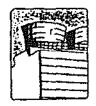
Under the Federal Insecticide, Fungicide, and Roderficids Act as amended, for the pesticide, registered under EPA Reg. No. 2 / 9 / 0 - 2 Manufactured by:

ALCO CHEMICAL DIVISION

Hattonal Starch and Chemical Company 909 Mueller Or. • P.O. Box 5401 • Chattanooge, TN 37406 423-629-1405 FAX 423-698-8723

> E.P.A. Establishment No. 31910-TN-1 E.P.A. Registration No. 31910-2 Net Contents: Liquid See Markings on Top of Drum for Net Weight

Cooling Towers and Air Washers



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its tabeling.

This product must not be used on any food or field crop or to formulate any product for use on any food or field crop.

See Technical Data Sheet(s) for additional use pattern(s).

INDUSTRIAL RECIRCULATING WATER COOLING TOWER AND EVAPORATIVE CONDENSERS

Dosage for industrial recirculating water cooling tower or evaporative condensers will depend on the condition of the system prior to treatment initiation. Systems which are fleavity contaminated should be cleaned first. Apply AQUATREAT DNM-30 to the cleaned system or when growth is first noticed, according to the following schedule: INITIAL DOSE: Apply 13.06-43.60 ounces of product per each 1000 gatlons of water in the system (120-400 ppm). This dose may be repeated once, twice or three times weekly or as required to control the growth of stime-forming organisms.

SUBSECUENT DOSE: When microbial control is evident add 2.18-4.36 Ituid ounces of AQUATREAT DNM-30 per t000 gallons of water (20-48 ppm) in the system every three days or as needed.

AIR WASHERS

In treating air washer systems preclean by introducing a suitable detergent solution into the system and attnw air washers to run with tan off for two hours. Check all nozzles and manualty clean those that are plugged.

Feeding: AQUATREAT DNM-30 may be ted directly from the drum or dituted with water and fed by any suitable teed system. AQUATREAT DNM-30 should be dosed directly into the sump or basin or any other location where good distribution can be assured.

INITIAL DOSE: Apply 13.06-21.80 ounces of product per each 1000 galloffs of water in the system [120-200 ppm]. This dose gray be repeated once, twice or three times weekly or as required to control the growth of silme-forming organisms.

SUBSEQUENT DOSE: When microbial control is evident add 2.18-4.36 fluid ounces of AQUATREAT DNM-30 per 1000 gallons of water (20-40 ppm) in the system every three days or as needed.

Drilling Hulds



Secondary and Tertiary Oli Recovery



DRILLING FLUIDS

AQUATREAT DNM-30 is a highly effective microbiocide for use in controlling growth of fungi and bacteria found in water based drilling muds. It is especially useful in muds containing starches, Xanthanate gums, and wood sugars. The uncontrolled growth of these fungi and bacteria can cause increased corrosion, undesirable odors, and degradation of the drilling mud, especially fluid loss properties.

AQUATREAT DNM-30 is used at the rate of 1 to 5 gations per t00 bbl. of mud. (0.02% to 0.1%). It can be used directly from the shipping container or pre-diluted with water. It can be put in through the mud hopper or added to the pump suction.

SECONDARY AND TERTIARY PETROLEUM RECOVERY

AQUATREAT DNM-30 is a highly effective microbiocide for use in controlling the growth of tungi and bacteria found in secondary and tertiary petroleum recovery waterflood systems.

AQUATREAT DNM-30 can be injected directly from the shipping container. It should be thoroughly mixed into the produced water, fresh or salt water or commingled water or the secondary or tertiary oil recovery waterflood systems for effective microorganism control. It may also be diluted with water for injection.

AQUATREAT DNM-30 is used at the rate of t pint per 100 bbl. of water for growth inhibition of Bacillus Cereus and Desultovibrio desulturicans and t.t to 1.8 gallons per 100 bbl. of water for heterofropic bacteria including Pseudomonas. It is also effective against many lungi such as Aspergillus, Penicillium and Trichoderma at the 1 pint per 100 bbl. of water.

FRACTURING FLUIDS

AQUATREAT DNM-30 is a highly effective microbiocide for controlling the growth of bacteria in tracturing fluids. The application rates are 0.8 t to 4.3 lbs. per 1000 gallons of fracturing fluids. AQUATREAT DNM-30 may be added end premixed prior to the fracturing operation or may be added directly from the drum to the blender during the operation.

WORKOVER & COMPLETION FLUIDS

AQUATREAT DNM-30 is a highly effective microblocide for use in controlling the growth of lungi and bacteria found in water based workover and completion fluids. AQUATREAT DNM-30 is used at the rate of 1-4 quarts per 1000 gallons (0.025%-0.100%) of workover or completion fluids.





FLUE GAS DESULFURIZATION (FGD) THICKENERS (NOT APPLICABLE IN CAUFORNIA)

THE RESERVE OF THE PROPERTY OF THE PARTY OF

AQUATREAT DNM-30 is effective in controlling anacrobic bacterla (SRB's) in flue gas desulturization (FGD) thickeners.

AOUATREAT DNM-38 is metered directly to the thickener center well. It is fed at the rate of 50 to 500 ppm of product on a frequency of all least once per week or as required.

HYDROCARBON FLUIDS

AQUATREAT DNM-30 is a highly effective fungicide and bactericide for use in fuel oil (No. 2 oil, intermediate fuel oil and No. 6 oil), lubricating oil and hydraulic fluids in marine environments.

AQUATREAT DNM-30 is applied initially at a level of 2.3 pints per 1000 gations of contaminated liquid (300 ppm by weight). Subsequent dosages may be decreased once the contaminants have been brought under control.

PAPER MILLS

Dosage will vary from 0.1 to 2.0 pounds (0.04 to 0.81 quarts) of AOUATREAT DNM-30 per ion of finished paper depending on the type of stock, complexity of the system, quality of raw water, and type and degree of contamination.

FEEDING: AQUATREAT DNM-30 may be drip fed continuously from the drum or fed by suitable chemical pumps such as adjustable proportioning types; variable speed, positive displacement types; or by the reciprocating type. This product should be fed as early as possible in the system at such points including the hydropulper, machine chest or broke system.

AQUATREAT DNM-30 can be used to control slime on machines which can make paper and paperboard for use in lood packaging.

BEET SUGAR MILLS

AQUATREAT DNM-39 should be ted directly into the pulp press water during sugar extraction of beets to keep equipment free of bacterial stime deposits; It is to be used at the rate of 10-20 ppm of raw beets sliced, and fed continuously with a metering pump. A portion of the AQUATREAT DNM-30 may be ted into other streams entering the diffuser each at a minimum rate of 4 ppm. The maximum total rate of all streams to be fed is 20 ppm. Refer to Composite Table 1 for the proper dosage in milliliters and ounces of AQUATREAT DNM-30 to be used per minute.

CANE SUGAR MILLS

AQUATREAT DNM-30 is a tiquid which should be led directly into the cane juice so that the treated juice circulates to all parts of the milt landem. The point or points of addition will depend on mill design. Frequently the dosage will be split between

the crusher juice and juice from the last mill. The best addition point is to the juice which is circulated back to the crusher from the first mill. Do not add this product to the maceration water.

AQUATREAT DNM-30 should be fed continuously at the rate of 10-20 parts of product per million parts of cane ground per day. 10 ppm of product is the standard dosage. This may be raised up to a maximum of 20 ppm, if necessary. Conditions warranting, some increase would be warranted when grinding cane damaged through freezing, poor weather or delays between cutting end grinding. See feeding directions which follow.

Proper feed of AQUATREAT DNM-30 is best obtained through the use of a chemical feed pump such as the adjustable proportioning type; the variable speed, positive displacement type; or the reciprocating type. The required dosage will depend on the average daity rate of cane ground. Refer to composite table I for the proper dosage in milliliters and ounces of AQUATREAT DNM-30 to be used per minute.

Do not exceed feed rate of 4 gallons (39.2 pounds) of product per 1000 short tons of cane ground per twenty-tour hours.

The use of AQUATREAT ONM-30 does not replace good housekeeping. This should include regular cleaning at least once per shift. Regular hosing with hot water and steam of mills, bagacillo conveyors, and screens is essential for maintaining efficient control of microbiological slime and sucrose losses.

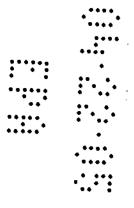
COMPOSITE TABLE I

SHORT TONS OF	Rate of Fe	ed of AQI	JATREAT	DHM-30		
CANE GROUND	10 p	pm i	20 ppm			
OR RAW BEETS						
SLICED PER DAY	m!/mfn	oz/min	ml/min	ez/៣៤		
1,000	5.5	D.186	11	0.372		
2,000	11.0	0.372	22	0.744		
3,000	16.5	0.558	33	1,115		
4,000	22.0	0.744	44	1.487		
5,000	27.5	0.930	55	1.859		
6,000	33.0	1.115	66	2.231		
7,000	38.5	1.301	77	2.603		
000,8	44.0	1.487	. 88	2,974		
9,000	49.5	1.673	99	3.347		
10.000	55.0	1.859	110	3.718		

For Chemical Emergency
Spitt, Leak, Fire, Explosive, or Accident
Call CHEMTREC — Day or Night
1-800-424-9300

Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material, when such use and/or handling is contrary to label instructions.

ATTACHMENT 1





			DUE DATE 5-00:	
CODING FORM F				
FILE SYMBOL/REG NO.	35900-2 PA	1 <u>33</u> ACTION	N CODE 302	
DESCRIPTOR		FQPA	NFQPA	
[] CHILD RESIST				
DATE ON APPLICAT	rion epa	RECEIVE DATE	PM RECEIVE DA	ATE
01/28/	<u>02</u>	102104	02/04/	D 4
METHOD OF [] CITE-ALL [[] NOT SUBMITTED [SUPPORT SELECTIVE			I TT ED
REVIEW(S) REQUESTED				
			J_4	_
BFFI CACY) [) (
ACUTE TOX.] [] [1 [4
RASSE TOX	J [] [,] [
ENVIRON. FATE] [] [
pish/wildlife] []	1 t	\
OTHER::] [] [
STATUS				<u>,</u>
RESFONSE C	ode <u>17</u>	RESPO	NSE DATE	904 4

CIENCE ROUP	DIVISION	BRANCH	SECTION	csf Y/N	LABEL Y/N		
'HEMISTRY	AD	EASSE	<u>CTT</u>		·····		
FFICACY	<u>a</u> D	<u>RASSB</u>	EET				
CUTE TOX_	<u>AD</u>	EASSE	CTT		·		
LISK TOX	AD	RASSB	TEAM 1				
EXPOSURE	AD	RASSB	TEAM 1				
NV. FATE	AD	RASSB	TEAM 2				
FISH/WILD_	AD	RASSB	TEAM 2				
-		NSTRUCTIONS CLUDE MRID#S					
INSTRUCTIONS							
	II	ISTRUCTIONS			······································		
					······································		
		······································					

Lewis & Harrison, Agent for Ionics, Inc. c/o 122 C Street, N.W. Suite 720 Washington, DC 20001

Attention: Christina M. Swick

Subject: HYgene

EPA Registration No. 35900-2

Amendment Application Dated: January 28, 2004

EPA Received Date: February 2, 2004

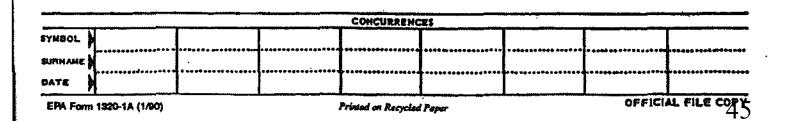
This will acknowledge receipt of your letter dated January 28, 2004, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, in response to PR-Notice 2001-1 "First Aid Statement". This information is acceptable and will be placed in subject product file.

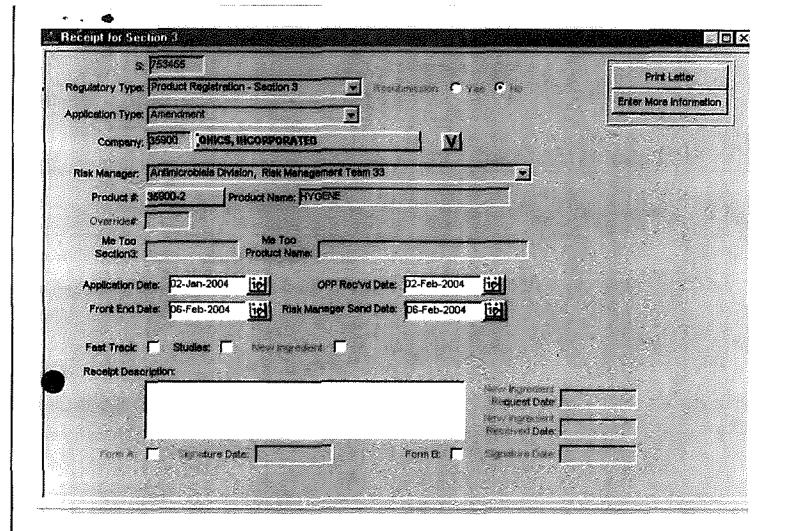
If your have any comments or questions concerning this letter, please contact me at 703-308-6341 or Portia Jenkins at 703-308-6230

Sincerely,

Marshall Swindell Product Manager (33)

Regulatory Management Branch I Antimicrobials Division (7510C)









SUBMISSION BAR C	ODE # 3 4	<u>, 1390.</u>	<u>2</u> REVIE	wer <u>klea</u> i	y-Munk
CODING FORM FOR	APPLICAT	CIONS FOR	REGISTR	ATION/AL	<u>endments</u>
FILE SYMBOL/REG NO			,	TION CODE	36L
[] CHILD RESISTA	ANT PACKAC	Fing: -[] []		DENTIAL U	
REGISTRATION TYPE	-			UNCONDITIO	
PROPOSED CLASSIFI	CATION:	[] GENER	AL [] :	restrictei	D USE
DATE ON APPLICATI	ON E	PA RECEIVE	DATE	PM RECE	IVE DATE-
. 04 8.3 02		4 63	02	0.4 0	5 02.
- METHOD-OF-SE	PPORT .	F	orm <mark>ulato</mark> ri	e- exempti	ON
[] NOT A					•
REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE:	DATE - RET URNES	ann <u>r</u>
CHEMISTRY		•		•	
EFFICACY		•.	·•	•	•
TOXICOLOGY		. ,			
· · HED TOX.	•	•			*
ENVIRON. FATE			•	•	· · ·
FISH/WILDLIFE	,		,		
OTHER				•	43°
			`	+	•
STATUS		<u> </u>	A4.%	· · · · · · · · · · · · · · · · · · ·	 .
FFFFONSS CODE	. /1		ESPONSE D		2 1 2002



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAY 2 1 2002

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Christina M. Swick, Agent for Ionics, Inc. Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017

Subject: HYgene Bacteriostatic Water Filter Media

EPA Registration Number 35900-2 Your Submission Dated April 3rd, 2002 EPA Received Date April 3rd, 2002

Dear Ms. Swick:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the alternate suppliers for the inert ingredient, activated carbon, for the basic formulation, and add an additional supplier of the active ingredient, is acceptable:

- Basic formula
- Data Matrix

Acceptable Data

The basic Confidential Statement(s) of Formula dated April 1st, 2002, is acceptable.

General Comments

Should you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)





Please read instructions on reve	rse before completing form.		Form Appi	oved, OMB No. 2070-	0060, Approval expires 05-31-98
A = n 4	United Sta	tes	□ Reai	stration	OPP Identifier Number
EPA	Environmental Prote	ection Agency		ndment	287810
45	Washington, DC			•	207010
		·········	☐ Othe		
	Appli	cation for Pes		ion I	
i. CompanyiProduct Number)	oduct Manager		Proposed Classification
35900-2 4. CompanyiProduct (Name)	-	Marshall PM#	Swindell		
HYgene Bacteriostatic Water	Filter Media	Team 33			None Restricted
5. Name and Address of Applic			lited Review.	In accordance wit	h FIFRA Section 3(c)(3)
lonics, Inc.					composition and labeling
3039 Washington Pike		to:			
Bridgeville, PA 15017	COBBEEDONINENICE TI	EPA Re	g. No	······································	
	<u>CORRESPONDENCE TO NT" LISTED BELOW</u>		Name	***************************************	
Check if this is a		/ roduct	Heilise	***************************************	
		Section			<u> </u>
N 1		260f(0)			
Amendment – Explain b			-	•	Agency letter dated
	nse to Agency letter dated		Me Too" Ap		
Notification - Explain be Explanation: Use addition		/Enr Section I	Other - Expi		
Explanation. Ose addict	mai page(s) ii necessar)	y. (For Section i	and Section in	··)	
_					•
F'(ormula Ameno	dment — I	Revised I	Basic Forn	ıula
		Section	ı III		
t. Material This Product Will Be					
Child-Resistant Packaging	Unit Packaging	\	Water Soluble Pac	xaging 2.	Type of Container
☐ Yes*	Yes No	1 1	Yes No		Metal Disease
L] NO	ti "Yes"	No. per	NO	No. per	Plastic Glass
*Certification must	Unit Packeging wgt.	- · · · · · · · · · · · · · · · · · · ·	Package wgt.	Paper	
be submitted	ļ		1	ļ	Other (Specify)
		1			
3. Location of Net Contents Info	-n	i) Retail Container		5. Location of La	bel Directions
Label L	Container				g accompanying product
6. Manner in Which Label is Af	fixed to Product Li	thograph	Other		g secompanying product
	🛄 Pi	aper glued			
	<u>□ s</u>	enciled			
		Section	_ iV		***
1. Contact Point (Complete it	ems directly below for identific	ation of individual fo	be contacted, if i	necessary, to process	ihis application)
Name		Title	" · · · · ·		elephone No. (Include Area Code)
Christina M. Swick, Lewis		4	Agent for lonle	s, Inc.	202-393-3903 x16
122 C Street NW Suite 740					6. Date Application
i certify that the stalements i.	Certification have made on this form and a		to are true accur	ate and complete 1	Received *****
acknowledge that any knowin	gly false or misleading statem				(Stamped) **
under applicable law.		CA TOU			****
2. Signature	W 1 " -1"	3. Title	gent for lonies.	Inc	••••
	M. Lurck		Rent for follies) IIIÇ.	****
4 Typed Name	I oncie & Harrison	5. Date	Aprit 3, 2002		:
Christina M. Swick, I	LACALIS OF LISTLESON		April 3, 2002		• ••

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete

White- EPA File Copy (original) Yellow- Applicant Copy

Please read instructions on reverse before completing form.	Form Appro	ved. OMB No. 2070-0060			
United States		Registration	OPP Identifier Number		
SEPA Environmental Protection A	gency	Amendment	287810		
Washington, DC 20460		Other	201010		
Application fo	r Pesticide - Secti	on i			
1. Company/Product Number	2. EPA Product Mena		oposed Classification		
			None Restricted		
4. Company/Product (Name)	PMS		None Resulted		
5. Name and Address of Applicant (Include ZIP Code)	•	W. In accordance with			
(to:	similar or identical in co	mposition and labeling		
\\	EPA Reg. No		<u> </u>		
Check If this is a new address	Product Name				
	ection - II				
\					
Amendment - Explain below.	Agency lette				
Resubmission in response to Agency letter deted	Me Too" Af	plication.			
Notification - Explain below.	Other - Expla	in below.			
Explanation: Use additional pagetal if necessary. (For section and	Seation II.)				
\					
\	\				
	\setminus /				
	X	"			
	étion - ili				
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging Unit Packaging Wa	ter Soluble Packaging	2. Type of Container	•		
	No \	Plastic			
H "Yee" No rey If "	Yes" No. per	Glass Paper			
bestubmitted Unit Packaging wgt. container Packaging wgt.	skege wgt container	Other i	Specify!		
3. Locotion of Net Contents Information 4/ Size(s) Retail Co	ntainer :	Location of Label Directi	one.		
Label Container	\	On Labeling secon	npanying product		
8. Manner In Which Label is Affixed to Product Lithograph	Other				
6. Manner in Which Labei is Affixed to Product Lithograph Paper glued Standied					
Section - IV					
1. Contact Point (Complete items directly below for identification of it	dividual to be contacted, it				
Name / Title		Telephon	e No. (Include Ares Code)		
	· · · · · · · · · · · · · · · · · · ·				
Certification ! certify that the atotements ! have made on this form and all attachments thereto are true, occurate and complete.					
t acknowledge that any knowingly false or misisading statement	may be punishable by fine	or imprisonment or	(Stamped)		
both under epplicable law. 2. Signature 3. Titl			• • • •		
(2. Signatura 3. Titi	•	*	·:•		
	<u></u>		Į:·. ·.		
4. Typed Name 5. Dat			[•••		
i			1		
			[

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Weshington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, atc. In order to proceed an application for a new registration submitted on this form, the following meterial must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exampted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft isbeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Metrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label, if prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please reed the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, raregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager if known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the isbei. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the parson or firm to whom the registration will be issued. If you are eating in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (a) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that ere similar or idendeal to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to emend the registredon only of a currently registered product (Amendment), for a resubmission in response to an Agency lotter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other ecdon that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "emend the Confidential Statement of Formula by..."; "reregistration submission"; "genging label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be compisted for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of peckeging. Check the appropriate black if your product will be packaged in the indicated packaging types.

 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents indicate the location of the net contents information for your product.
- 4. Sipple) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions indicate the location of the use directions for your product.
- 6. Manner in which jakel is affixed to product indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-top," registration, atc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Res	ect to Citation of Data				
Applicant's/Registrant's Name, Address and Telephone Number	EPA Registration Number/ File Symbol				
Iontes Inc.: 3039 Washington Ptke, Bridgeville, PA 15017 / 202-3	3-3903 (Agent) 35900-2				
Active Ingredient(s) and/or representative test compound(s):	Date				
Silver (EPA A.I.# 72501)	April 3, 2002				
General use pattem(s) (list all those claimed for this product using 40 C					
Aquatie Food Crop	HYgene Bacteriostatic Water Filter Medla				
NOTE: If your product is a 100% repackaging of another purchased E do not need to submit this form. You must submit the Formulator's Exe					
I am responding to a Data Call-in Notice, and have included with Matrix form should be used for this purpose).	his form a list of companies sent offers of compensation (the Data				
SECTION I: METHOD OF DATA S	JPPORT (Check one method only)				
1 am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).				
SECTION II: GENEI	AL OFFER TO PAY				
[Required if using the cite-all method or when using the cite-all option u	der the selective method to satisfy one or more data requirements]				
I hereby offer and agree to pay compensation, to other persons, wire FIFRA.	regard to the approval of this application, to the extent required by				
SECTION III: C	RTIFICATION				
I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of that would be required to be submitted under the data requirements in effect on the date of approval of this application if the distance of identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of t I have obtained the written permission of the original submitter to cite	is registration or reregistration, that I am the original submitter or that hat study.				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1](F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to derify *** cancel or suspend the registration of my product in conformity with FIFRA.					
i certify that the statements t have made on this form and acknowledge that any knowingly false or misleading statements mapplicable law.					
Signature (1) - OOA Date	Typed or Printed Name and Title				
Signature Christina M. Lurole April 3, 20	Christina M. Swick - Agent for Ionics Inc.				
EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only	Paner version				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

04/05/2002

CHRISTINA M. SWICK, AGENT FOR IONICS, INCORPORATED 122 C STREET, NW, SUITE 740 WASHINGTON DC 20001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: HYGENE BACTERIOSTATIC WATER FILTER MEDIA

COMPANY NAME: LEWIS & HARRISON FOR IONICS

OPP IDENTIFICATION NUMBER: 287810 EPA REGISTRATION NUMBER: 35900-2 EPA RECEIPT DATE: 04/03/2002

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Marshall Swindell, Product Manager 33, at (703)-308-6230.

Sincerely,

runce

Front End Processing Staff Information Services Branch Program Management and Support Division



IONICS, INCORPORATED

BRIDGEVILLE PLANT

O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE

BACTERIOSTATIC WATER FILTER MEDIA EPA REGISTRATION NO. 35900-2

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from municipally treated tap water
- . Inhibits the growth of bacteria within the media bed to prolong the life of the filter

ACCEPTED with COMMENTS in EPA Letter Deted:

MAR | 3 |995

Under the Legentia avortide. registered under LPA log. No.

WHAT IT IS AND HOW IT WORKS

The physical characteristics of Hygene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in Hygene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Bacteriostatic Water Filter Media is to be used only for manufactufing or fabricating bacteriostatic water filter products for home use. Filter : manufacture for home use. facturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 0.5 gpm per 0.25 lb. of media. Bed depth must be at least twice the diameter.

Use on cold water only.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the KPA.

SPECIFICATIONS

ACTIVE INCREDIENT

INKRT INGREDIENT

Metallic Silver - 1.05%

Activated Carbon - 98.95%

STORAGE

Store in closed container with excludes moisture and chemical fumes.

MESH SIZE

PACKAGING

12 X 30 U.S. Sieve Series

6 Cu. Pt. Piber Drums 1 Cu. Ft. Carton

0r

20 x 50 U.S. Sieve Series

SHIPPING POINT

34 Lbs. Per Cubic Foot

Bridgeville, Pennsylvania

PROPERTY PAPERS

WKTGHT.

- 4/6/9# PROPERTY

ACCEPTED with COMMENTS in EPA Letter Dated: MAR | 3 1995

Under the Percupt terreticide, registered under EPA Reg. No.

35900-2



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

· WOO.

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT METALLIC SILVER1.05% LOT NO. _ **INERT INGREDIENT** ACTIVATED CARBON......98.95%

, cu. ft.

DIRECTIONS FOR USE:

NET CONTENTS Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice the diameter.

DISPOSAL OF SPENT MEDIA:

Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General lonics Water Conditioning Equipment IONICS, INCORPORATED 3039 Washington Pike, Bridgeville, Penna. 15017



UNITED STATES E RONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460



Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40f M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRI	X			
Date April 3, 2002			EPA Reg. No./File Symbol 3590	90-2	Page f of f	
Applicant's/Registrant's Name & Address: Ionics, Inc. 3039 Washington Pike, Bridgeville, PA 15017			Product HYgene Bacteriostatic Water Filter Media			
Ingredient(s): Silver (A.I.# 725				····	···········	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
61-1 to 62-3	Product Identity, Composition and Analysis				Wajycd	
63-2 to 63-9	Physical/Chemical Properties				Waived ¹	
71-1(a)	Acute Avian Oral Toxicity - Quail/Duck	CITE-ALL	See Attachment	PAY		
71-2(a)	Avian Dietary Toxicity - Quail/Duck	CITE-ALL	See Attachment	PAY		
71-2(b)	Acute Avian Dietary - Duck				Waived ¹	
72-1(a)	Freshwater Fish Toxicity - Bluegill				Waiyed	
72-1(c)	Fish Toxicity - Rainbow Trout	CITE-ALL	See Attachment	PAY		
72-2(a)	Freshwaler Invertebrate Toxicity	CITE-ALL	See Attachment	PAY		
81-1	Acute Oral Toxicity				Waiyed	
81-2	Acute Dermal Toxicity				Waived ¹	
81-3	Acute Inhalation Toxicity				Waived ¹	
81-4	Primary Eye Irritation				Waivcd ¹	
81-5	Primary Dermal Irritation				Waived ¹	
6-18	Skin Sensitization				Waived!	
161-1 to 165-5	Environmental Fate				Waived	

FOOTNOTE:

f. These data requirements were waived under the provisions of the Silver RED (June 1993).

	•		•	
•			• •	-
•			_	•
			•	• • •
*		•		
			-	• •
			•	
•	•			

Signature Chinsina M. Lurcle

Name and Title: Christina M. Swick, Agent for Ionics, Inc. Date April 3, 2002

Agency Internal Use Copy

DATA MATRIX ATTACHMENT

Product Name:

HYgene Bacteriostatic Water Filter Media

EPA Reg. No.: Date of Data Matrix:

35900-2 April 3, 2002

Chemical:

Silver, A.I. Number 72501

COMPANY# 008588 RGDEN FILTER COMPANY INC * DATA TYPES * 4662 LANKERSHIN BLVD. EU AT EC FW EF OT NORTH HOLLYWOOD CA XX 91602

COMPANY# 010324 MASON CHEMICAL CO * DATA TYPES * 721 W ALGONQUIN RD EU AT EC FW EF OT ARLINGTON HEIGHTS IL XX 60005

COMPANY# 014944 ATEK INDUSTRIES INC * DATA TYPES * 5355 MCCONNELL AVE EU AT EC FW EF OT LOS ANGELES CA XX 90066

COMPANY# 018869 KING-HOLLER INT * DATA TYPES * 606 WILSHIRE BLVD SUITE 501 EU AT EC FW EF OT SANTA MONI CA XX XX 90401

COMPANY# 035968 CONSUMER ECOLOGY PROD., INC * DATA TYPES * 101 S. W. FIFTH COURT EU AT EC FW EF OT POMPANO BEACH FL XX 33060

COMPANY# 037370 NATIONAL SAFETY ASSOCIATES, INC. * DATA TYPES * 4260 EAST RAINES ROAD EU AT EC FW EF OT MEMPHIS TN XX XX 38118

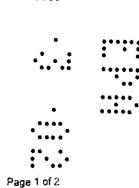
COMPANY# 037664 TELEDYNE WATER PIK * DATA TYPES * 1730 EAST PROSPECT ST EU AT EC FW EF OT FORT COLLINS CO XX XX 80521

COMPANY# 037756 WATER SAFE PRODUCTS, INC * DATA TYPES * 8337 NIEMAN ROAD EU AT EC FW EF OT LEXEXA KS XX 66214

COMPANY# 038058 PUROLATOR CA. PUROLATOR, INC. * DATA TYPES * 950 RANCHO CONEJO BLVD. EU AT EC FW EF OT NEWBURY PARK CA XX 91320

COMPANY# 038688 C. H. DEXTER DIVISION * DATA TYPES * ONE ELM STREET EU AT EC FW EF OT WINDSOR LOCKS CT XX XX 06096

COMPANY# 039444 SUUNTO USA INC AGENT FOR: KATADYN PRODUCTS, INC. * DATA TYPES * 2151 LAS PALMAS DRIVE, SUITE F EU AT EC FW EF OT CARLSBAD CA XX XX 92009



DATA MATRIX ATTACHMENT

Product Name:

HYgene Bacteriostatic Water Filter Media

EPA Reg. No.: Date of Data Matrix: 35900-2 April 3, 2002

Chemical:

1

Silver, A.I. Number 72501

COMPANY# 039938 NORTH AMERICAN SYSTEMS, INC.

* DATA TYPES * 24700 MILES ROAD EU AT EC FW EF OT BEDFORD HTS. OH

XX XX 44146

COMPANY# 067712 ZODIAC POOL CARE, INC.

* DATA TYPES * 3420 NORTHWEST 53RD STREET

EU AT EC FW EF OT FT. LAUNDERDALE FL

XX XX 33309

COMPANY# 071227 AGION TECHNOLOGIES LLC

AGENT FOR: SINANEN COMPANY, LTD.

* DATA TYPES * 60 AUDUBON ROAO

EU AT EC FW EF OT WAKEFIELD MA

XX XX 01880

COMPANY# 071661 SRA INTERNATIONAL, INC.

AGENT FOR: INTELLIGENT BIOCIOES LLC

* DATA TYPES * 1850 M STREET, N.W., SUITE 290

EU AT EC FW EF OT WASHINGTON DC

XX XX XX 20036

COMPANY# 072977 HENRY JACOBY, REGULATORY CONSULTANT

AGENT FOR: ETI H2O, INC.

* DATA TYPES * 6709 ILEX COURT

EU AT EC FW EF OT NEW MARKET MD

XX XX 21774

COMPANY# 073148 SCIENTIFIC & REGULATORY CONSULTANTS

AGENT FOR: ISHIZUKA GLASS CO., LTD.

* DATA TYPES * 102 1/2 SOUTH CHAUNCEY STREET

EU AT EC FW EF OT COLUMBIA CITY IN

XX 46725

COMPANY# 073499 AMERICAN BIOTECH LABS

* DATA TYPES * 70 WEST CANYON CREST RD., SUITE O

EU AT EC FW EF OT ALPINE UT

XX 84004

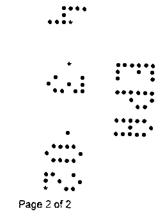
COMPANY# 073667 CHEMREG INTERNATIONAL, LLC

AGENT FOR: APYRON TECHNOLOGIES, INC.

* DATA TYPES * 2239-H TACKETS MILL ORIVE

EU AT EC FW EF OT LAKE RIDGE VA

XX 22192





UNITED STATES E RONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460



Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 (37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX Page 1 of 1 April 3, 2002 EPA Reg. No./File Symbol 35900-2 Date Applicant's/Registrant's Name & Address: Product Ionics, Inc. 3039 Washington Pike, Bridgeville, PA 15017 HYgene Bacteriostatic Water Fifter Media Ingredient(s): Silver (A.I.# 72501) Guideline Reference Number Guideline Study Name MRID Number Status Note Submitter Waived Waived See Attachment PAY See Attachment PAY Wai ved¹ Waived PAY See Attachment PAY See Attachment Waived) Waived! Waived Waived Waived1 Waived Waived

		•	
	::	• •	•
	• • •	•	•••
• •		• -	• :
•	•		ē

Signature

Name and Title: Christina M. Swick, Agent for ionics, inc. Date April 3, 2002

DATA MATRIX ATTACHMENT

Product Name:

HYgene Bacteriostatic Water Filter Media

EPA Reg. No.: Date of Data Matrix: 35900-2 April 3, 2002

Chemical:

Silver, A.I. Number 72501

COMPANY# 008588 RGDEN FILTER CDMPANY INC

* DATA TYPES * 4662 LANKERSHIN BLVD.

EU AT EC FW EF OT NORTH HOLLYWOOD CA

XX 91602

COMPANY# 010324 MASON CHEMICAL CO
* DATA TYPES * 721 W ALGONQUIN RO
EU AT EC FW EF OT ARLINGTON HEIGHTS IL
XX XX 60005

COMPANY# 014944 ATEK INDUSTRIES INC
* DATA TYPES * 5355 MCCONNELL AVE
EU AT EC FW EF OT LOS ANGELES CA
XX 90066

COMPANY# 018869 KING-HOLLER INT

+ OATA TYPES * 606 WILSHIRE BLVD SUITE 501

EU AT EC FW EF OT SANTA MONI CA

XX XX 90401

COMPANY# 035968 CONSUMER ECDLOGY PROD., INC DATA TYPES * 101 S. W. FIFTH COURT EU AT EC FW EF OT POMPANO BEACH FL XX 33060

COMPANY# 037664 TELEDYNE WATER PIK

DATA TYPES * 1730 EAST PROSPECT ST

AT EC FW EF OT FORT COLLINS CO

XX XX 80521

COMPANY# 037756 WATER SAFE PRODUCTS, INC * DATA TYPES * 8337 NIEMAN ROAD EU AT EC FW EF OT LEXEXA KS XX 66214

COMPANY# 038058 PUROLATOR CA. PUROLATOR, INC.

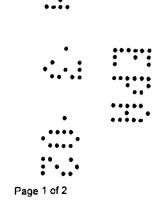
* DATA TYPES * 950 RANCHO CONEJO BLVD.

EU AT EC FW EF OT NEWBURY PARK CA

XX 91320

COMPANY# 038688 C. H. DEXTER DIVISION * DATA TYPES * ONE ELM STREET EU AT EC FW EF OT WINDSOR LDCKS CT XX XX 06096

COMPANY# 039444 SUUNTD USA INC
AGENT FOR: KATADYN PRODUCTS, INC.
* DATA TYPES * 2151 LAS PALMAS DRIVE, SUITE F
EU AT EC FW EF OT CARLSBAD CA
XX XX 92009



DATA MATRIX ATTACHMENT

Product Name:

HYgene Bacteriostatic Water Filter Media

EPA Reg. No.: Date of Data Matrix: 35900-2 April 3, 2002

Chemical:

Silver, A.I. Number 72501

COMPANY# 039938 NORTH AMERICAN SYSTEMS, INC.

* DATA TYPES * 24700 MILES ROAD EU AT EC FW EF OT BEDFORD HTS. OH

XX XX 44146

COMPANY# 067712 ZODIAC POOL CARE, INC.

* DATA TYPES * 3420 NORTHWEST 53RD STREET

EU AT EC FW EF OT FT. LAUNDERDALE FL

XX XX 33309

COMPANY# 071227 AGION TECHNOLOGIES LLC

AGENT FOR: SINANEN COMPANY, LTD.

* DATA TYPES * 60 AUDUBON ROAD

EU AT EC FW EF OT WAKEFIELD MA

XX XX 01880

COMPANY# 071661 SRA INTERNATIONAL, INC.

AGENT FOR: INTELLIGENT BIOCIDES LLC

* DATA TYPES * 1850 M STREET, N.W., SUITE 290

EU AT EC FW EF OT WASHINGTON DC

XX XX XX 20036

COMPANY# 072977 HENRY JACOBY, REGULATORY CONSULTANT

AGENT FOR: ETI H2O, INC.

* DATA TYPES * 6709 ILEX COURT

EU AT EC FW EF OT NEW MARKET MD

XX XX 21774

COMPANY# 073148 SCIENTIFIC & REGULATORY CONSULTANTS

AGENT FOR: ISHIZUKA GLASS CO., LTD.

* DATA TYPES * 102 1/2 SOUTH CHAUNCEY STREET

EU AT EC FW EF OT COLUMBIA CITY IN

XX

XX 46725

COMPANY# 073499 AMERICAN BIOTECH LABS
* DATA TYPES * 70 WEST CANYON CREST RD., SUITE D

EU AT EC FW EF OT ALPINE UT

84004 XX

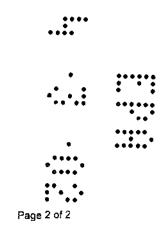
COMPANY# 073667 CHEMREG INTERNATIONAL, LLC

AGENT FOR: APYRON TECHNOLOGIES, INC.

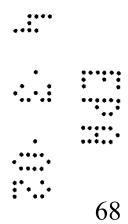
* DATA TYPES * 2239-H TACKETS MILL DRIVE

EU AT EC FW EF OT LAKE RIDGE VA

XX 22192

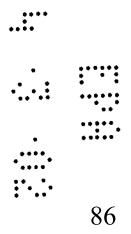


ATTACHMENT 1





ATTACHMENT 2





			~~ ~		- cym	-00				ON-F	
SUBMI	SSION	BAR	CODE	# <u>5.3</u>	374	<u> </u>	_ R	evi ewe r	1-1	<u> </u>	7
DING	FORM	FOR	APP	LICAT	CIONS	FOR	REGI	STRAT:	ION/AI	MENDM	ENT
				_	_		~				

CODING FORM FOR P	PPLICAT	IONS FOR	REGISTE	RATION/AM	ENDMENTS
FILE SYMBOL/REG NO .3.	5900-0	2 PM 3	3 <u>3</u> A0	CTION CODE	350
DESCRIPTOR PRA	letice	2000	-3		<u>.</u>
[] CHILD RESISTA	NT PACKAG		CERTIFIC NON-RESI	IDENTIAL US	SE ONLY
REGISTRATION TYPE	: [] C	ONDITIONAL	(· ·)	UNCONDITIO	NAL
PROPOSED CLASSIFI	CATION:	[] GENER	AL []	RESTRICTE	USE
DATE ON APPLICATION	ON E	PA RECEIVE	DATE	PM RECE	VE DATE
10 17 08		18 ZO	00	10 8	300
METHOD OF SU	PPORT	F	ORMULATO	RS EXEMPTIO	ÒИ
[] NOT A]] NOT	ITTED SUBMITTED APPLICABLE RRECT/RESUE	3
REVIEW(S) REQUESTED	DATA PACK #	DATE SENT	DUE DATE	DATE RETURNED	
CHEMISTRY					
EFFICACY		* · · · · · · · · · · · · · · · · · · ·	-		
TOXICOLOGY					
HED TOX.					
ENVIRON. FATE					
FISH/WILDLIFE				- 	
OTHER,	3,11,1				
STATUS				· · · · · · · · · · · · · · · · · · ·	•

RESPONSE CODE 37 RESPONSE DATE NOV 0 2 2000



P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE 412-257-2029 FAX 412-257-1270

October 17, 2000

U.S. Environmental Protection Agency Office of Pesticides Programs Registration Division (7504C) 401 M St., S.W. Washington, D.C. 20460

Attn:

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division (7505C)

Re:

PR Notice 2000-3

lonics Product Registration Numbers: 35900-2; 35900-3; 35900-6; 35900-7; 35900-9;

35900-13; 35900-16; 35900-18; 35900-19; 35900-20 and 35900-21

Dear Mr. Swindell:

Pursuant to the above referenced PR Notice 2000-3 regarding First Aid Statements on Pesticide Product Labels, I am sending this letter as a formal confirmation of my communications and discussions with your Ms. Karen Leavy-Munk.

Basically, the above referenced products' labels only require the precautionary statement "Keep Out of Reach of Children" above the signal word "Caution", which already appears on all of our labeling. Additionally, we are to follow Toxicity Category IV across the board in regards to First Aid Statements due to the only active pesticide ingredient being Silver.

With this formal confirmation, shortly we will be forwarding our present labels with any modification required by Toxic Category IV, as outlined in the above referenced PR Notice, to your offices for review and acceptance.

Thank you for your continued support and guidance in our registration of product through the U.S. EPA.

Sincerely,

Ionics, Incorporated

John Henigin

Manager, Chemical Products and Projects

			Reviewer I	D		1 - 11 1	
			Submission	No.	54	90 66	/_
			Data Packa	ge No.			
CODING FORM FOR APPLICAT	IONS FOR REX	ISTRATION	/AMENIONENTS				
File Symbol/Reg. No. $\frac{36}{10}$			L 1	ion cod Je cl		<u> 320</u> h.	
				<u> </u>	7/0	<u>.</u>	
13 Micrastate Carrell			Packaging	anc <u>/</u>		Certificat	
20 Registration Type:	/ <u></u> / (N) I	40 .				Service Pe	
(1) Conditiona	. —	/2\ Uncon	dikinant	<i>!</i>	_/ (R)	Non-reside Use Onl	
25 Proposed Classifica				_	/ (N)	Not-Applic	able
/// (R) Restricte	d <u>//</u>	(R) Restri	cted				
/// (G) General	\Box	(N) Not C	assified				
Date on Application of DAY	<u>s</u> To	PA Receive	ed Date: 295	7.81	6 2	ived by PM 2 9 3 AY YR	
80 Method of Support	:1						
// (I) Cite-All	<u>//</u> (6) Owner Si	ubmission -				
(4) Not Applicabl	le <u>//</u> (7) Total S	ubmission		٠.	The sa	
// (5) Not Submitted	1 // (8) Selection	ve Method			**************************************	
Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	33 <u>00</u>	EPONSE DE	RESPONSE DATE	
СН							
EF							
PL				 			
DEB							
NDEB	<u> </u>			<u></u>			
TB				***************************************			
EEB						<u>.</u>	
EFGB			1				
III5 FINAL Response	2 ()	-	1 <u>170</u> Rest×x	٠ ۶ .	7/	895	

104

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 18

Ionics, Inc. 3039 Washingotn Pike Brideville, PA 15017

Attention: Walter J. Polens

Subject: Hygene

EPA Registration Number 35900-2 Your Submission Dated June 22, 1995 EPA Received Date June 22, 1995

The submitted final printed labels have been placed in your product file. They have not been reviewed in accordance with the PR Notice 82-2.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,

Marion J4 Johnson Product Manager (31)

Antimicrobial Program Branch Registration Division (7505C)

CONCURRENCES				
SYMBOL)				
SURNAME				***************************************
DATE				
EPA Form 1320-1A (1/90)	<u> </u>	Printed on Dervoled Benev		OFFICIAL FILE COPY

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

A U.S. GOVERNMENT PRINTING OFFICE 1995 4 9 404

HYgene®

BACTERIOSTATIC WATER FILTER MEDIA

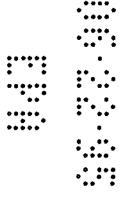
- •This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water.
- This product is designed to inhibit the growth of bacteria within the filter to prolong the life of the filter.

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA REGISTRATION NO. 35900	-2 EPA ESTABLISHMENT NO. 35900 PA 01
ACTIVE INGREDIENT Metallic Silver 1.05%	LOT No.
INERT INGREDIENT Activated Carbon98.95%	NET CONTENTScu. ft,
STORAGE	Store in closed container which excludes moisture and chemical fumes.
DISPOSAL OF SPENT MEDIA	When contents are exhausted, wrap in newspaper and discard in the trash.
DIRECTIONS FOR USE-	Refer to enclosed product data sheet.

IONICS, INCORPORATED. 3039 WASHINGTON PIKE, BRIDGEVILLE, PA 15017







O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE BACTERIOSTATIC WATER FILTER MEDIA EPA REGISTRATION NO. 35900-2 EPA ESTABLISHMENT NO. 35900 PA 01

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

- •This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water.
- This product is designed to inhibit the growth of bacteria in the filter to prolong the life of the filter

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual function of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating Bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are respansible for providing data to the United States Environmental Protection Agency to support the registration of their products.

SEE REVERSE SIDE

HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the in service flow rate is not to exceed 0.5 gpm per 0.25 Lb. of media. Bed depth must be at least twice the diameter.

USE WITH COLD WATER ONLY.

SPECIFICATIONS

ACI	IVE	INGREDIENT	

INERT INGREDIENT

Metallic Silver - 1.05%

Activated Carbon - 98,5%

STORAGE

Store in closed container which excludes moisture and chemical furnes.

MESH SIZE

PACKAGING:

20 X 50 U.S. Sieve Series

6 Cu. Ft. Fiber Drum 1 Cu. Ft. Carton.

WEIGHT

SHIPPING POINT

30-34 Lbs. Per Cubic Foot

Bridgeville, Pennsylvania



3/1/95

And the second s					
A CONTRACTOR OF THE SECOND	111111		Reviewer II) Thirties and stiffen	
	The state of the state of the	of the state of	Submission	No.	yperites.
	•		Data Packag	ge No. 些	
CODING FORM FOR APPLIC	ATIONS FOR	REGISTRATI	ON/AMENIMENTS		
File Symbol/Reg. No. 2			2	on Code 6	3
$ \overline{10} $ Descriptor (Amend	/Resubulsio	ns only)		·	
5 Intrastate Call-i	n (Y) Yes <u>15</u>	Child-resista	int(C) Certification
	(H) No .	Packaging		S) Service Person
[20] Registration Type	:				R) Non-residential
(1) Condition	na) _	7 (2) Una	onditional		Use Only
25 Proposed Classific	eation: $ \overline{30} $	Final Cla	assification:		N) Not-Applicable
(R) Restrict	ed	(R) Rest	ricted		
(G) General	سب		Classified		
Date on Applicate of Applicate		EPA Receiv	ved Date:	40 Date Re	ceived by PM
80 Method of Suppor	t:			~ (2	ted Ik
(1) Cite-All	77	(6) Owner:	Submission .		
(4) Not Applicat				e,	
(5) Not Submitte		8) Selecti			The state of the s
Reviewers Requested:	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
CH					
EF					
PL				}	
DEB					
ире8					
TB					
EEB					
EFGB		The second secon			
ACTION Code	٧		:170 Respons	031	395
75-DAY RESPONSE DUE DAT		205	11.	***	<u>.</u>

DATE OF ISSUANCE EPA REGISTRATION NO. US ENVIRONMENTAL PROTECTION AGENCY MAR 13 35900-2 OFFICE OF PESTICIDES PROGRAMS TERM OF ISSUANCE REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: REGISTRATION RENEGISTRATION Hygene (Under the Fodorel Insociicide, Fungicide, end Rodenticide Act, as omendedi NAME AND ADDRESS OF REGISTRANT (Include ZIP code). Ionics, Inc. 3039 Washington Pike Bridgeville, PA 15017 NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerco. In any correspondence on this product always refer to the above U.S. EPA registration number. On the basis of information furnished by the registrant, the above named pesticide is heraby Registered/Reregistered under the Federei Insecticide, Fungicide, and Rodenticide Act. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Registration is in no way to be construed as an indorsement or approval of this product by this Agency, in order to protect heelth and the environment, the Administrator, on his motion, may at say time suspend or cancel the registration of a peatleids in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant e right to exclusive use of the name or to its use if it has been covered Based on your response to the Silver Reregistration Eligibility Document, EPA has reregistered the above named product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product. Make the following labeling changes before you release the product for shipment: Make the following labeling changes listed below before you release the product for shipment: a. Add the phrase *EPA Registration No. 35900-2* b. Include the appropriate EPA Establishment No. c. Revise the statement "Removes....tap water" to read "This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water."

EPA Form 8570-6 (Rev. 5-76)

ATTACHMENT IS APPLICABLE

PREVIOUS ROITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CONCURAENCES								
SYMBOL)						*********	*	
EURHAME)								
DATE								
EPA Form 1320-1A (1/90)		Printed on Recycled Paper			OFFICIAL FILE COPY			

- d. Delete the phrase "General Classification" to read "Directions for Use."
- e. Revise the statement "Inhibits the growthfilter media" to read "This product is designed to remove objectionable tastes, odors, and color from municipally treated tap water."
- f. Place the statement "Keep Out of Reach of Children" directly above the signal word "Caution."
- g. Place the misuse statement "It is a violation of the Federal Law to use this product in a manner inconsistant with its labeling" directty under the subheading "Directions for Use."
- h. Delete the phrase "Filters suspended solids" from the product labeling.

The Confidential Statement of Formula dated April 11, 1994, is in compliance with PR Notice 91-2, it agrees with the label and is acceptable.

The label claim is in compliance with PR Notice 91-2 which is the nominal concentration and it agrees with the Confidential Statement of Formula and is acceptable.

A stamped copy of the labeling is enclosed for your records.

Submit one copy of final printed labeling before releasing the product in channels of trade with the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Sincerely,

WS

Walter C. Francis Acting Product Manager (31) Antimicrobial Program Branch Registration Division (7505C)



R.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE

BACTERIOSTATIC WATER FILTER MEDIA EPA REGISTRATION NO. 35900-2

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

. Removes objectionable tastes, odors, and color from municipally treated tap water

. Inhibits the growth of bacteria within the media bed to prolong the life of the filter

ACCEPTED
with COMMENTS
in EPA Letter 12 ted:

MAR | 3 | 1995

Universitie Letter in desemblie. Eachtrick der Schale der Schale Brightlick der Schale der Schale Teglisteren ander Letter Kop. No.

WHAT IT IS AND HOW IT WORKS

35900-2

The physical characteristics of HYgene Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a buildup or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of mutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

Hygene Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

HYGENE BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 Lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 0.5 gpm per 0.25 lb. of media. Bed depth must be at least twice the diameter.

Use on cold water only.

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

SPECIFICATIONS

ACTIVE INGREDIENT

INERT INGREDIENT

Metallic Silver - 1.05%

Activated Carbon - 98.95%

STORAGE

Store in closed container with excludes moisture and chemical fumes.

MESH SIZE

PACKAGING

12 X 30 U.S. Sieve Series Or 6 Cu. Ft. Fiber Drums

20 x 50 U.S. Sieve Series

1 Cu. Ft. Carton

MRIGHT

SHIPPING POINT

30-34 Lbs. Per Cubic Foot

Bridgeville, Pennsylvania

CHANGE OF THE PROPERTY OF THE PARTY OF THE P

A-11-1

4/6/94

ACCEPTED with COMMENTS in EPA Letter Dated: MAR 1 3 1995

Under the Privat Insecticide, registered under EPA Reg. No.



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT METALLIC SILVER1.05% LOT NO. **INERT INGREDIENT** ACTIVATED CARBON......98.95%

DIRECTIONS FOR USE:.....

DISPOSAL OF SPENT MEDIA:.....

NET CONTENTS Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least twice

the diameter. Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment IONICS, INCORPORATED 3039 Washington Pike, Bridgsville, Penna. 15017

DATE	OUT:		
------	------	--	--

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:

OR AN END-USE PRODUCT [] a manufacturing-use [v]

DP Barcode 12/1584 Reg. No. or File Symbol No. 35900-2

TO:

(PM Team Reviewer)

PM Team No: 31 Walter Francis / Karen Leavy

FROM:

(Chemist/Date) Anna Skanara Product Chemistry Review Section

Registration Support Branch/RD (WH705W)

THRU:

Harold Podall, Ph.D., Section Head

Registration Support Branch/RD (WH7505W)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Confidential Statement of Formula dated 4-11-94 is in compliance with PR Notice 91-2, it agrees with the label and is acceptable.

Label ingredient Statement is in compliance with PR Notice 91-2 it is the nominal concentration, it agrees with Confidential Statement of Formula and is acceptable.

anna Skapars

	/
PROD DP B. PROD	UCT CHEMISTRY REVIEW OF MP [1] EP [] ARCODE No.: 1)211584 REG./File Symbol No.: 35900-2 UCT NAME: Hygene Bactarostatic Water Telter Media
1.	Reviewer: Anna Skapanz. Company: Ionics, Inc.
3.	Type of Submission: Registration [] Reregistration [/] New [] Resubmission [] Amendment [] "ME-TOO" [] Alternate Formulation [] Experimental Use Permit [] Other (Specify)
4.	If "Me-TOO" Registration, this product is [] is not [] similar or substantially similar to EPA's Reg. No.:
	If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.
CONF	IDENTIAL STATEMENT OF FORMULA
5.	Type of formulation and the sources of active ingredients:
	 Non-integrated formulation system
	• Integrated formulation system
6.	Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
	Formulation intended for food use under 40CFR\$180.1001: • yes [] • no [] • Some are cleared, others are not [] Cleared under list: • c[] • d[] • e [] Are there any limitations for use as an inert under 40CFR\$180. 1001? • yes [] • no [], If yes, specify //A
	Ass () A no (), it has becith the
6 (b)	Formulation intended for non-food use: • yes [√] • no [] • Some are cleared, others are not []
6 (c)	Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and [b) substances generally recognized as safe (GRAS).

anna.

DP BARCODE: D211584

CASE: 019229 SUBMISSION: S480969 DATA PACKAGE RECORD

BEAN SHEET

DATE: 02/02/95 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 675

RESUBMISSION

PROJ DATE:

RANKING : 10 POINTS () CHEMICALS: 072501 Silver

CHEMICALS: 072501 Silver 01.0500%

ID#: 035900-00002 HYGENE

COMPANY: 035900 IONICS, INCORPORATED

PRODUCT MANAGER: 31 WALTER FRANCIS 703-305-6661 ROOM: CM2 248
PM TEAM REVIEWER: KAREN LEAVY 703-305-6966 ROOM: CM2 268

RECEIVED DATE: 01/13/95 DUE OUT DATE: 07/12/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 211584 EXPEDITE: N DATE SENT: 02/02/95 DATE RET.: / /

CHEMICAL: 072501 Silver

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 05/03/95 DIV: RD // NEGOT DATE: //

DIV: RD // // BRAN: RSB // // SECT: PCRS // // // PRUP: Care &/ // //

REVR: anna Skapail, //
CONTR: 2-7-95

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised Confidential Statement of Formula and Product Labeling in response to the Silver RED. Attn: Anna Skapars

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

DP BARCODE: D211584

CASE: 019229 DATA PACKAGE RECORD DATE: 02/02/95

SUBMISSION: S480969 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 675 RESUBMISSION

RANKING : 10 POINTS ()

CHEMICALS: 072501 Silver 01.0500%

ID#: 035900-00002 HYGENE

COMPANY: 035900 IONICS, INCORPORATED

PRODUCT MANAGER: 31 WALTER FRANCIS 703-305-6661 ROOM: CM2 248
PM TEAM REVIEWER: KAREN LEAVY 703-305-6966 ROOM: CM2 268

RECEIVED DATE: 01/13/95 DUE OUT DATE: 07/12/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 211584 EXPEDITE: N DATE SENT: 02/02/95 DATE RET.: / /

CHEMICAL: 072501 Silver

OP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 05/03/95

REVR: // // // CONTR: // //

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised Confidential Statement of Formula and Product Labeling in response to the Silver RED. Attn: Anna Skapars

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

DP BARCODE: D211584

CASE: 019229 DATA PACKAGE RECORD DATE: 02/02/95

SUBMISSION: S480969 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 675 RESUBMISSION

RANKING : 10 POINTS ()

CHEMICALS: 072501 Silver 01.0500%

ID#: 035900-00002 HYGENE

COMPANY: 035900 IONICS, INCORPORATED

PRODUCT MANAGER: 31 WALTER FRANCIS 703-305-6661 ROOM: CM2 248
PM TEAM REVIEWER: KAREN LEAVY 703-305-6966 ROOM: CM2 268

RECEIVED DATE: 01/13/95 DUE OUT DATE: 07/12/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 211584 EXPEDITE: N DATE SENT: 02/02/95 DATE RET.: / /

CHEMICAL: 072501 Silver

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 05/03/95

REVR : / / / / / / / CONTR: / / / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised Confidential Statement of Formula and Product Labeling in response to the Silver RED. Attn: Anna Skapars

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL



United States Environmental Protection Agency Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS Approval Expires 12-31-92

Form Approved

OMB No. 2070-0106

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE, PA 15017	Company Number 35900 PA 01
Chemical Name		EPA Chemical Number
	SILVER	072501

Certify that:

- 1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
- That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)
 - All companies on the data submitters' list for the active ingredient listed on this form (Cite-All Method or Cite-All Option under the Selective Method). (Also sign the General Offer to Pay below.)
 - [] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
- That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies f have cited in support of registration or reregistration under FIFRA.

Signature	Dete
There Peles	APRIL 11, 1994
Name and Tille (Please Type or Print)	•••••
WALTER J. POLENS, VICE PRESIDENT	

GENERAL OFFER TO PAY: It hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature .	Dale	•••	••••
1. Hold Pole	APRIL 11,	1994	****
Name and Titla (Please Type or Print)		•	
WALTER J. POLENS, VICE PRESIDENT		··	



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE 412-343-1040 FAX 412-257-1270

KPA REREGISTRATION

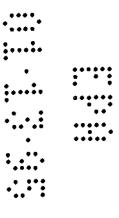
PHASE 5 RESPONSE. SILVER AND COMPOUNDS CASE NO. 4082, CHEMICAL NO. 072501

EPA REG. NO. 35900-2 (MANUFACTURING USE PRODUCT)

HYGENE BACTERIOSTATIC WATER FILTER MEDIA

ENCLOSED

- (1) OUR COMPLETED APPLICATION FOR REGISTRATION EPA FORM 8570-1
- (2) COMPLETED CONFIDENTIAL STATEMENT OF FORMULA EPA FORM 8570-4
- (3) COMPLETED CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS EPA FORM 8570-31
- (4) FIVE (5) COPIES OF OUR REVISED DRAFT LABEL AND LABELING
- (5) PRODUCT QUALITY CONTROL PROCEDURE USED TO DETERMINE THE PERCENTAGE OF THE ACTIVE INGREDIENT SILVER. LABEL CLAIM PERCENTAGE IN THIS PRODUCT IS A NOMINAL CONCENTRATION AS REQUIRED BY THE AGENCY.



)	Application	Programs (H76) 1, DC 20460 1 for Pesti	Agency 08C) Cide:	Reg	gistrati endm	on C	PP Identific	3034
ļ		Section I	EPA Product Ma					iffaati
	1. Company/Product Number 35900-2	2.	JOHN H. LE			3. Pros	osed Class	MCEUON
	4. Company/Product (Name) HYGENE BACTERIOSTA WATER FILTER MEDIA	ATIC PN	31			X	ione	Restricted
	5. Name and Address of Applicant (Include ZIP Code) 10NICS, INCORPORATED 3039 WASHINGTON PIKE P.O. BOX 99 BRIDGEVILLE, PA 15017 Check if this is a new address	(b) to	Expedited Revi(I), my product: A Reg. No oduct Name	is similar o	r Identica	al in com	position a	nd labeling
	S	ection I I						
	Amendment - Explain below		Final printed		onse to			
	Resubmission in response to Agency letter dated		"Me Too" App					,
)	Notification - Explain below.	X	-			ICATI GISTR	ON FOR ATION	
	DOCUMENT FOR CASE NO. 4082 SILVER	R AND COMP	OUNDS.					
	Sec	tion III						
	Material This Product Will Be Packaged in:	da, e						٠.
	Child-Resistant Packaging Unit Packaging	· I	ble Packaging	2. 1	ype of Co			
	Yes X	Yes				etal Astic		
	X No No	X No				228 1901	v	
	* Certification must be Unit Package wgt. No. per	_ list.ii	No. ; gt. contr			ther (Spe	cify)	<u>, </u>
N	submitted. 34 LB. 1							
		of Retail Contail		5. Locatio	n of Label Label	Direction	15	
	[V] F836 F Couraines	ograph			Labeling	accompa	nying produ	ect
	X Pag	ographi nailed	Cthe	r (- (· · · · · · · · · · · · · · · · · · ·)
		ection IV						
ŀ	Contact Point (Complete items directly below for identifical Name	tion of individua	to be contacted,	il necessary				Area Code)
	WALTER J. POLENS JOHN D. COLLINS	VICE P	RESIDENT R, LABORAT	ORY			343-50	
	Certificat I certify that the statements I have made on this form and a I acknowledge that any knowingly false or misleading state both under applicable law.	l attachments t				1	Date Appl Received (Stamp	
	2, Signature	3. Title			·		••••	
	The Pre-	VICE	PRESIDENT				:.::-	
	4. Typed Name WALTER J. POLENS	5. Date APRII	11, 1994	Mid-17			•:••	100
ı	PA Form 8570-t (Rev. 12-90) Previous editions are ob	solete.	White - EPA	File Copy	(original)	Y	ellow - Ap	plicant copy

PAPERMORK REDUCTION ACT MOTICE and INSTRUCTIONS

PAPERMORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. in order to process an application for a new registration submitted on this form, the following material must accompany the applications:

i. Certification with Respect to Citation of Data (EPA form 2570-29). | It not exempted by 40 CFR 152.81 (b) (4));

Confidential Statement of Formula (EPA Form 8570-4);
 Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted; Authorization letter where applicable;

7. Natrices where applicable.
Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5×11 inch file. Mockup labels significantly smaller than 8.5×11 inches should be mounted on 8.5×11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections 1, 111, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, rangistrations, atc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a besic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Humber.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Ciacaification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are ecting in behalf of another perty, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for thom in all registration matters. The name and complete mediing address of such an agent must accompany this application.

6. Expedited Review - FIFRA saction 3 (c) 3 (B) provides for expedited review of applications for registration, or assendments to existing registrations; that are similar or identical to other pasticide products that are currently registered with the EPA. In order for your application to be sligible for expedited review, you must provide us with the EPA Registration Humber and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to smend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency Letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered

product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(a) for the submission, such as "the addition of a site, pest or crop (specify)"; "assend the Confidential Statement of Formule by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in completed for with new registration or applicable amendments.

Type of Packinging - Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the alse of the individual packets and number per retail container.
 Type of Backets Container - Indicate type of container in which product will be merketed.

3. Location of Not Contents - Specify the net contents of all retail containers for your product. '4.' Sign(a) of Retail Container - Specify the net contents of all retail containers for your product.

5. Location of Use Directions - Indicate the location of the use directions for your product.

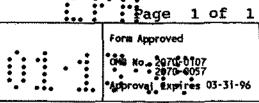
6. Maker in which label is affixed to product - Indicate the method product label is ettached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.a., now products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory. 6. EPA Use OPTY

United	States	Environmen	ntal	P3	rotection	Agency
	Wa	shington,	D.	c.	20460	

DATA CALL-IN RESPONSE



INSTRUCTIONS: Please type or print in Ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(a) if necessary.

1. Company name and Address IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE PA 15017 2. Case # and Name 4082 Silver, and cmpds. 3. Date and Type of DCI PRODUCT SPECIFIC

4. EPA Product	5. I wish to	6. Generic Data		7. Product Specific Data	
Registration	cancel this product regis- tration volun- tarily.	6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. i agree to mutisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. Ny product is a MUP and I agree to satisfy the MUP requirements on the attached form entitied "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response,"
35900-2		N.A.	N.A.	YES	
	:				
	4				
8. Certification				9. Date	

or	both	under	sppl	108016	(BW.				
	_	_		_		_	_		

Signature and Title of Company's Authorized Representative_

i certify that the statements made on this form and all attachments are true, accurate, and complete. l acknowledge that any knowlingly false or misleading statement may be punishable by fine, imprisonment

10, Name of Company Contact

WALTER J. POLENS, VICE PRESIDENT

NOVEMBER 24, 1993

ii. Phone Number

412-343-1040

Page 1 of

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

ONS No. 2970-0107
2970-0057
Approved Exgires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the ottached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Hame 4082 Silver, and cmpds.

EPA Reg. No. 35900-2

3. Oate and Type of DCI PRODUCT SPECIFIC ID# 35900-RD-3186

							<u>_</u>		
4. Guidei ine Requirement Kumber	5. Study Title	0		Progr 10qs		6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
RUNDET		Įğ	1	2	3				
	Prod Chem - Regular Chemical								
61-1	Product identity & composition(1)					ABCDEFGHIJKL M NO	MP/EP	8 mos.	7
61-2(a)	Descrip of attring materials;(1,2) production & formulation					ABCDEFGHIJKIMNO	MP/EP and TG/	AI 8 mos.	19.00 m
61-2(b)	proc Discussion of formation of (1,3)				X	ABCDEFGHIJKLMNO	MP/EP and TG/	AI 8 mos.	4230
62-1	ispurities Praliminary analysis (1,4)					abcdrfghijklmno			7
62-2 62-3	Certification of Limits (1,5) Analytical method (1)					ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP MP/EP	8 mos. 8 mos.	7
63-2 63-3	Color Physical state				¥	ABCDEFGHIJKIMNO ABCDEFGHIJKIMNO	MP/EP and TG		
63-4 63-5	Odor Kelting point (6)					ABCDEFGHIJKIMNO ABCDEFGHIJKIMNO	MP/EP and TG		
63-6 63-7	Bolling point (7)					ABCDEFGHIJKIMNO ABCDEFGHIJKIMNO	TGAT	8 mos.	7

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete.

) acknowledge that any knowingly folse or misleading statement may be punishable by fine, imprisonment

or both under applicable law.

Signature and Title of Company's Authorized Representative

12. Hame of Company Contact

WALTER J. POLENS. VICE PRESIDENT

11. Date

NOVEMBER 24, 1993

13. Phone Number

412-343-1040

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

ONS No. 2070-0107
2070-0057

Approvide Experses 03-31-96

Page 2 of 3

INSTRUCTIONS: Please type or print in ink. Please read cersfully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Name 4082 Silver, and cmpds.

EPA Reg. No. 35900-2

3. Date and Type of DCI PRODUCT SPECIFIC ID# 35900-RD-3186

4. Guideline Requirement	5. Study Title	800		Progr Repor		6. Use Pattern	7. Test Substance	8. 11me Frame	9. Registrant Response
Runber		Ę	1	2	3			Į.	
63-8 63-9	Solibility Vapor pressure		*********	1000		ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO		8 mos. 8 mos.	7
63-10 63-11	Ölggeclation cometent Octanol/water partition (8)					abcobeeghtjklmno abcobeeghtjklmno		8 mos. 8 mos.	7
63-12	coefficient p# (9)			2000000000	. Marcon	ABCDEFGHIJKLMNO			7
63=13 63=14	Stability Oxidizing or reducing action (10)					ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP	8 mos. 8 mos. 8 mos.	7
63-15 63-16 63-17	flammeblilty (11) Explodability (12) Storage Stability			. ,		ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP	8 mos.	7
63-18 63-19	Viscosity (13) Misciplity (14)				1,000	ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP	8 mos. 8 mos.	7, 3
63-20 63-21	Corrosion cheracteristics Dislectric brestdown voltage (15)					ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP	8 mos. 8 mos.	7
	Acute Texts - Results Chesical								
81-1 81-2	Acute drai toxicity-rat (1,36,37) Acute dermal (1,2,37)				*****	ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO			
81-3	toxicity-rabbit/rat Acute inhalation toxicity-rat (3)					ABCDEFGHIJKLMNO			7

initial to indicate certification as to information on this page (full text of certification is on page one).

Date

NOVEMBER 24, 1993

Page 3 of 3

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

ONS No. 2620-0107
2070-0057

Approgal Egpires 03-31-96

LMSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(a) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Memo 4082 Silver, and cmpds. 3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 35900-RD-3186

EPA Reg. No. 35900-2

M15027 1111 Ft. 13017			 		7. 33300 &	<u> </u>			
4. Guideline Requirement Humber	5. Study Title	20-00	Progr Repor	te 3	6. Use Pattern	7. Yest Substance	5. Time Frame	9. Registrant Response	
81-4 81-5 81-6	Primary dermal irritation (1,2)	1			Abcdefghijklmno Abcdefghijklmno Abcdefghijklmno	MP/EP	8 mos.	7	
							Andrew Prince and Andrew Princ		
,								Marin and the state of the stat	

fulfile to indicate certification as to information on this page (full text of certification is on page one).

NOVEMBER 24, 1993

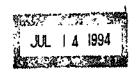
Date

Sal

Data Package No. CODING FORK FOR APPLICATIONS FOR REGISTRATION/AMENIMENTS Action Code 674 File Symbol/Reg. No. 35900-2 PM 31 10 Descriptor (Amend/Resubmissions only) & morth Mesponse |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant 7(C) Certification Packaging (N) No /(S) Service Person |20| Registration Type: (R) Non-residential Use Only /// (1) Conditional /// (2) Unconditional (N) Not-Applicable | 25 | Proposed Classification: | 30 | Final Classification: 7 (R) Restricted $/\overline{}$ (R) Restricted (G) General (N) Not Classified |35| Date on Application: |04| EPA Received Date: 40 Date Received by PM |80 | Method of Support: / (6) Owner Submission . (4) Not Applicable (7) Total Submission / (5) Not Submitted / / (8) Selective Method DATE DUE DATE RESPONSE RESPONSE Reviewers Requested: SENT DATE RETURNED CODE DATE CH EF PL DEB NDEB TB EEB **EFGB** Response 4 115 FINAL 120 Response 75-DAY RESPONSE DUE DATE: //(Y) Yes / /(N) No

129

Sissi · Joseph Co.



MEMORANDUM

Subject: Request to Issue a Notice of Intent to Suspend (NOITS)

to Registration of Silver Products for Failure to Respond to the <u>Silver RED</u> 8-month DCI as Required under FIFRA

Section 3 (c) (2) (B).

FROM: Juanita Wills, Chief

Antimicrobial Program Branch Registration Division (7505C)

TO: Frances Liem, Chief

Laboratory Data Integrity and Compliance Branch Office of Enforcement and Compliance Assurance

(EN-342W)

The Antimicrobial Program Branch (APB) requests that a 3(c) (2) (B) Notice of Intent to Suspend (NOITS) be issued to those registrants of Silver products who <u>failed to respond</u> to the required 8-month Data Call-In (DCI) Notice in the Reregistration Eligibility Document (RED) for Silver, Case 4082.

The Silver RED required that the registrants of pesticide products containing Silver meet certain data requirements to maintain continued registration of product(s).

The registrants listed below were sent the Silver RED upon issurance August 8, 1993. As of the date of this letter, these registrants have <u>failed to respond</u> to the 8-month DCI. Certified mail receipt cards (green cards) were received from all registrants who were mailed the RED. Submitted as an attachment to this memo are copies of each registrants' green card showing receipt of the Silver RED document on or near August 12, 1993.

The 8-month DCI response required submission of an application for reregistration, a Confidential Statement of Formula (CSF), Certification Form, revised labeling, and submitting or citing, product-specific chemistry and acute toxicity data. Failure to adequately respond to the 8-month DCI for this RED is a basis for the Agency to issue a NOITS.

If you have any further questions regarding this matter, please contact Karen Leavy at (703)-305-6966.

Attachments

cc: Walter Francis
Marshall Swindell

APB requests that a 3 (c) (2) (B) NOITS letter be issued to each of the registrants listed below for failure to respond to the 8-month DCI for the Silver RED. The registrants' complete name and address and registration number, is provided as follows:

1) Registrant: Pazianos Association

Agent For: Everpure, Inc.

1338 G Street, SE Washington, DC 20003

EPA Reg. Nos.: 2623-4 and 2623-5

2) Registrant: Barnebey & Sutcliffe Corporation

EPA Reg. Nos.: 58295-1, 58295-2, and 58295-3

3) Registrant: BesTech, Inc.

EPA Reg. Nos.: 37589-2, 37589-4, 37589-5 and 37589-6

ź

4) Registrant: Ionics, Inc.

EPA Reg. Nos.: 35900-2, 35900-3, 35900-6, 35900-7,

35900-9, 35900-12, 35900-13, 35900-16 and

35900-18

5) Registrant: National Safety Associates

EPA Reg. Nos.: 44751-1, 44751-2, 44751-3, 44751-4,

44751-5, 44751-7, 44751-8, 44751-9,

44751-10, and 44751-11.

	•			SUSE	102
•	**	• *		Reference to	UPDET.
•••					Cuca /
COOLING FORK FOR APPLICA					
File Symbol/Reg. Ho.	5900-7	2 px. <u>3/</u>	(B) Acti	on code 670	
10 Descriptor (Amend/	Resultations	only) W	NAY BODGE	a balver	ED/ DATA
[Intrastate Call-in	(Y)	Yes (<u>13</u>	Child-resists	ne(c)	Care MEV DE
•	/ (H) (No	Packaging		Service F
[20] Registration Types				(R)	Honoresid
[] (1) Condition	al 📿	(2) Undan	ditional	,	Use Cr
Exposed Classific	ectons (30)	rinel Clas	al Licectons	<u></u>	Hot-Appli
(R) Restrict	≈	(R) Rástri	cted		ĺ
(G) General		(H) Hoe CI	bellians		
135 Oxes on Applicate 11 1 2 4 9	3 7	PA Receive	9.9.3	1 1 2 7	18 18 18 18 18 18 18 18 18 18 18 18 18 1
(0) Hethad of Suppose	t:				•
(1) CICENTI	<u> </u>) Owner Si	ubalisation	Dona	
(4) Not Applicab	ia 👉 (7	1 Total S	utwission	1704	10
(5) Not Submitte	d 📿 () Selecti	ve Hethod		_
Reviewers Requestads	OATE SOUT	CAIR	ONTE RETURNED	000E 802E040E	SESPORG STAG
<u>. 60</u>					
PH					·
PC.					
CII					
EF					
IM Status					
ITISI FIRIL Response	71	*. ·	ITXI Respon	·/12 1	20,93

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

OMS No. 2070-0107 2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address IONICS, INCORPORATED 3039 WASHINGTON PIKE BRIDGEVILLE PA 15017

- 2. Case # and Name 4082 Silver, and cmpds.
 - EPA Reg. No. 35900-2

3. Date and Type of DCi PRODUCT SPECIFIC ID# 35900-RD-3186

4. Guideline Requirement	5. Study Title	5. Study Title		5. Study Title			Progress Reports		6. Use Pattern	7, Test Substanc	7. Test Substance		9. Registren Response	ŧ
Number		δ	1	2	3		! 		<u></u>					
	Prod Chem - Regular Chemical						, i							
											-03-48* 			
61-1	Product identity & composition(1)	l				ABCDEFGHIJKLMNO			8 mos	• 7				
61-2(a)	Descrip of starting materials; (1,2)	1				ABCDEFGHIJKLMNO	MP/EP	and TGAI	8 mos	. 7				
	production & formulation	<u>.</u>												
	próc								1		14.77			
61-2(b)	Discussion of formation of (1,3)					ABCDEFGHIJKLMNO	MP/EP	and TGAI	8 mos	. 7				
	impurities													
62-1	Preliminary analysis (1,4)			1	.,.,.	ABCDEFGHIJKLMNO	MP/EP	and TGAI	8 mos	• 7				
62-2	Certification of limits (1,5)					ABCOREGHIJKLANO	MP/EP		8 mos	. 7				
62-3	Analytical method (1)			Ĭ		ABCDEFGHIJKLMNO	MP/EP		8 mos	. 7				
63-2	Color					ABCDEFGHLJKLMNO	MP/EP	and TGAI	8 2008	. 7				
63-3	Physical stote		J			ABCDEFGHIJKLMNO	MP/EP	and TGAI	8 mos	**** 7				
63-4	Ottor					ABCDEPGHIJKIMNO				, L 7				
63-5	Heiting point (6)		Ī	f*****	paranet prices	ABCDEFGHIJKLMNO		■ MANUSOSAN REPORT NEWS PROFITS	A mos					
63-6	Boiling point (7)		**************************************			ABCDEFGHIJKIMNO			.8 mos					
63-7	Density		2000000	venaki.		ABCDEFGHIJKLMNO				stated and devote the contract of the contract	11 0122			
		<u>L_</u>	<u> </u>	<u> </u>	<u> </u>				1					
10. Certification								11. Date	**					

10.	Cer	tif	icat	ion
-----	-----	-----	------	-----

I certify that the statements made on this form and ail sttachments are true, accurate, and complete.

I acknowledge that any knowledgy faise or misleading statement may be punishable by fine, imprisonment

or both under applicable law.

Signature and Title of Company's Authorized Representative

12. Name of Company Contact

WALTER J. POLENS, VICE PRESIDENT

NOVEMBER

13. Phone Kumber

412-343-1040

sesponse

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

ONS No. 2070-0107 2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Name 4082 Silver, and cmpds. 3. Date and Type of DCI PRODUCT SPECIFIC ID# 35900-RD-3186

EPA Reg. No. 35900-2

4. Guideline Requirement	5. Study Title			Prog Repo		6. Use Pattern	7. Test Substance		8. Time Frame		9. Regi	istrant se
Humber	ALEXT:		8	1 2	3							
63-8	Solubitity					ABCDEFGHIJKIMNO	TGAI/PAI		8 mos	3	7	
63-9	Yapor pressure	I	T			ABCDEFGHIJKLMNO			8 mos	5.	7	
63-10	Dissociation constant					ABCDEFGHIJKLMNO			8 mo	s.	7	` .
63-11	Octanol/water partition (8	s)				ABCDEFGHIJKLMNO	PAI		8 mos	s.	7	
	coefficient				1753							eri veriliy
63-12	pH (9))			l .	ABCDEFGHIJKLMNO		TGAI	8 mos	s.	7	
63-13	Stabil(ty					ABCOMFGHIJKIMNO			8 moi	5.	7	
63-14	Oxidizing or reducing action (1	10)			<u>.</u>	ABCDEFGHIJKLMNO			8 mos		7	
63-15		1)				ABCDEFGHIJKIMNO			8 mo:	5.	7	
63-16		[2)	1]	ABCDEFGHIJKLMNO			8 mo		. 7	
63-17	Storage stability					ABCDEFGHIJKIMNO			8 moi	S.	7	
63-18		(3)	. L		l	ABCDEFGHIJKLMNO			8 mos	ş.	. 7.	
63-19	Hiscibility (1	4)	4			ABCDEFGHIJKLMNO			8 mos	5	. 7	
63-20	Corrosion characteristics				<u>l</u> ,	ABCDEFGHIJKLMNO			8 mos	I	. 7	
63-21	Dielectric breakdown Voltage (1	5)				ABCDEFGHIJKLMNO	MP/EP		···& moi	3	7	
	Acute Toxic - Resulter Chesical											
81-1	Acute oral toxicity-rat (1	,36,37)				ABCDEFGHIJKIMNO	MP/EP and	TGAT	B mo			2:4693
81-2	The second section of the second seco	,2,37)	.770 (C.S.)	1917 ST 1818 ST 1818	* 00000000	ABCDEFGHIJKLMNO					7	
	toxicity-rabbit/rat			w i ne						******		
81-3	Acute inhalation toxicity-rat (3	5)		3/400 \$500 (160	1.600.000	ABCDEFGHIJKLMNO	MP/EP and	TGAI	8 mo:	s : 1	. 7	
					<u>L</u>							
initial to indicate ce	rtification as to information on this	page				' Date				• _ •	. •	SA

Initial to indicate certification as to information on this page (full text of certification is on page one).

NOVEMBER 24, 1993

Page 3 of 3

United States Environmental Protection Agency Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved

CMS No. 2070-0107 2070-0057

Approval Expires 03-31-96

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
IONICS, INCORPORATED
3039 WASHINGTON PIKE
BRIDGEVILLE PA 15017

2. Case # and Hame 4082 Silver, and cmpds.

PRODUCT SPECIFIC
ID# 35900-RD-3186

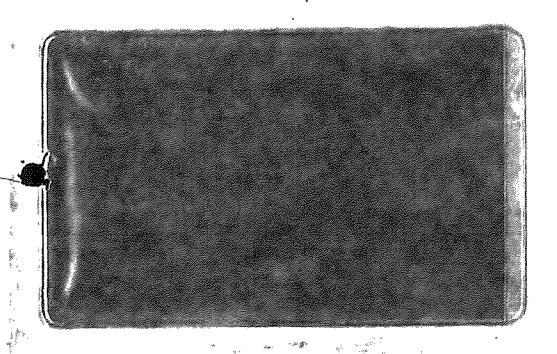
3. Date and Type of DC1

EPA Reg. No. 35900-2

4. Guideline 5. Study Titio Requirement Number		oc Oc	<u> </u>	Reports		6. Use Pattern	7. Teat Substance	8. Time Frame	9. Registrant Response
81-4 81-5 81-6	Primary eye irritations rabbit (2) Primary dermal irritation (1,2) Dermal sensitization (4)	C	1	2]	ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO ABCDEFGHIJKLMNO	MP/EP	8 mos. 8 mos. 8 mos.	7 7
									•

Initial to indicate certification as to information on this page (full text of certification is on page one),

NOVEMBER 24, 1993



035900-00002



P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERALCLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS



ACTIVE INGREDIENT

Silver (as AgNO₃) - 1.05%

INERT INGREDIENT

Activated Carbon - 98,95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

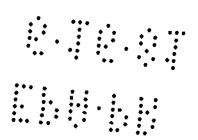
6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania



Ionics, Incorporated P.O. Box 99 Routes 519 & 50 Bridgeville, PA 15077

Attention: Walter Polens

Gentlemen:

Subject: Bygene Bacteriostatic Water Filter Media EPA Registration No.: 35900-2 Amendment Application Date: June 12, 1981

A preliminary review of the subject application has been made. However, before the amendment can be processed further, clarification is needed in the following regard.

(a) Please explain if 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate Your label accepted October 29, 1975 declared "Netallic Silver - - - 1.05%."

1 .

- (b) Is it the same product? Please clarify.
- (c) If your label declares "silver" from "silver nitrate" then you may declare no more than 0.67%. Explain why you wish to change your formulation?

Sincerely,

John H. Lee Product Manager (31) Disinfectants Branch

Registration Division (TS-767C)

EPA:TS-767C:JHLEE:46073:1725A:479-2018:7/6/81

				Record Nu	mber 4.342/
				Reference	Humber 2
CODING FORM FOR AP	DITCSTINS	EUB SECIELA	TION/AMENDMENTS	Input	t Date 7-2/-8/
1 File Symbol/Reg.	3590	U-2 r		Action Gode <u>⊆</u>	300
Fill bile symbothes.					
5.Intrastate Call-	in //	(Y)Yes			
3421101 23 68 40 441 .		(N)No			
7.Child-resistant	· 7		istration Type:		
// (Y)Yes /			/ (1)Conditio)Unconditional
9.Proposed Classif			nal Classificat	ion:	
// (R) Restr		/_	/ (R)Restric	ted // (N)Not Classified
(G) Genera	11	/_	/ (G)General		
Date on Applica	tion: [Z EPA Receiv	ed Date:	13 Date Rece	ived by PM.
16 / 6 MO DAY	8/	KO /	1681 DAY YR	MO	/ 7 8
MO DAY 20.Method of Suppo		, nu		fication State	
// (1)Cite-A	11 //	(4)Not Appl	icable //	(1)Yes //	(3)Not Applicable
// (2)Aİtern	ate /X/	(5)Not Subm	itted /	(2)Not Submitt	ed
// (3)Combin	ed /				
Za Reviews Requested:		•			
	DATE	DUE DATE	DATE. RETURNED	RESPONSE CODE	RESPONSE DATE
ing an					
ra				12	6-26-81
PL		·		·	
CH					
EF					
26 Status:			·		
77 FINAL Resp	onse /)	Respoi Date	ise 017/	1/10//	
ACTION: Code		uate		DAY YR	
[28] 75-DAY RESPON	ISE DUE DAT	E: / /(Y)	Yes / /(N)N	9	141

TECHNICAL SUPPORT SECTION CHEMISTRY REVIEW - II Disinfectants Branch

EPA Reg. No. or File Symbol 35900-2
Dara Divísion Raceived
Products Manager No. 3/(Lee_)
Product Name Hygene Mark I Bacteriostatic Water Filter Mid
Comment Innies, Inc
Comments:
a. Please explain of 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate Your label accepted Oct 29, 1975 declared "Metallic silver 1.05%." Is it the same ploducit? Please clarify. If your label declars "silver" from "silver nitrate" than you may declare no nisce than 0.67%. Explain who, you wish to change your formulation?
6-25 81 anna Skapar

4,	ENFORCEMENT CAS	E KFAIEM
O: Director, F	Pesticides Enforcement Division	I.O. NO. 172045
	Inforcement and General Counsel	EPA REGISTRATION NO.
RODUCT HAME ((On esimple tabet)	See below
	. BACTERIOSIATIC WATER UNIT	
OMPANY HAME	AND ADORESS (On sample label) (Include ZIP code)	REGISTRATION STATUS AT TIME OF
Bon Del	Inc.	X Collection
	ROSEROY	TEGISTERED
Mass, A	Z 85202	NOT REGISTERED
	OISTRIBUTOR STATUS AT TIME OF	SHIPMENT (I(applicable)
ASIC PRODUCT !	NAME	PRODUCT SUPPLEMENTALLY REGISTERED
Son.		☐ ¥£1 ☐ NO
TRANT NAL	ME ANO AODRESS (Include 21P code)	DATE OF SUPPLEMENTAL REGISTRA
Man Benevius	IT REGISTRATION OATA	
Dan Del register They have 43430-E	METATIC WHITE UNIT is registered to lile, MA. 15017 for product name HTG Inc., Mass. AZ 85202 (company numbered under EFA Reg. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TRY, (3) 63430-G	THE under EFA Reg. No. 35900-2. If 43430) is not supplementally y have no registered products.
Dan Del register They have 43430-E	MATIC WHER UNIT is registered to Lile, M. 15017 for product name HTG Inc., Mesa, AZ 85202 (company numbered under EFA Bay. No. 35900-2. The	ENGLE, Inc., P.O. Box 99, ENE under EPA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for NO. DEL MOST. B.1 (2)
Dan Del register They have 43430-E	METATIC WHIRE UNIT is registered to ille, MA. 15017 for product name HTG Inc., Mesa, AZ 85202 (company numbered under EPA Beg. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TWO, (3) 63430-G mions dated 10-16-79).	ENGLE, Inc., P.O. Box 99, ENE under EPA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for NO. DEL MOST. B.1 (2)
Dan Del register They have 43430-E	MATTIC WATER UNIT is registered to lile, MA. 15017 for product name HTG Inc., Mesa, AZ 85202 (company numbered under EFA Reg. No. 35900-2. The three applications pending (1) 43 for BOH DEL MODEL TWI, (3) 63430-G micros dated 10-16-79).	ENGLE, Inc., P.O. Box 99, ENE under EPA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for NO. DEL MOST. B.1 (2)
Pringer Bon Del They have 43430-E This a Pesticil Sticioe Claims	Inc., Mesa, AZ 85202 (company makes and trader ETA Bag. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TRY, (3) 63430-G micros dated 10-16-79).	ENNICS, Inc., P.O. Box 99, ENE under EMA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for HON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
Pringer Bon Del They have 43430-E This a Pesticil Sticioe claims	Inc., Mesa, AZ 85202 (company makes and trader ETA Bag. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TRY, (3) 63430-G micros dated 10-16-79).	ENNICS, Inc., P.O. Box 99, ENE under EMA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for HON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
Pringer Bon Del They have 43430-E This a Pesticil Sticioe claims	EMATIC WHEN UNIT is registered to lile, M. 15017 for product name HTG INC., Mesa, AZ 85202 (company names and under EMA Reg. No. 35900-2. The three applications pending (1) 43 for BOH DEL MODEL TWI, (3) 63430-6 micras dated 10-16-79).	ENNICS, Inc., P.O. Box 99, ENE under EMA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for HON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
Pringer Bon Del They have 43430-E This a Pesticil Sticioe claims	Inc., Mesa, AZ 85202 (company makes and trader ETA Bag. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TRY, (3) 63430-G micros dated 10-16-79).	ENNICS, Inc., P.O. Box 99, ENE under EMA Reg. No. 35900-2. r 43430) is not supplementally y have no registered products. 430-P. for NON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
THIS A PESTICINESTICIOE CLAIMS	Inc., Mesa, AZ 85202 (company makes and trader ETA Bag. No. 35900-2. The three applications pending (1) 43 for BON DEL MODEL TRY, (3) 63430-G micros dated 10-16-79).	ENNICS, Inc., P.O. Box 99, THE under ETA Reg. No. 35900-2. If 43430) is not supplementally y have no registered products. 430-P. for HON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all) (e. L.

	RECORD OF TELEPHONE CALL OR VISITOR
	INCOMING CALL D - VISITOR - 9/12/79
	Mr. J.W. Southwick
	DEAL Dept. of Health COMPANY TEL NO. (Include A rea Code) REGISERATION NO. OF FILE SYMBOL
	DATE OF LATEST SUBMISSION
	BAR SUMMARY OF CONVERSATION QUESTIANS About Has Putifier
	Pts Bax Del Ho Parifier Registered 2-NO-
_	- Registereasinos
	It says it uses "EPA
	Registered Media 35901-2
	Number 35980 - PA OI Prob. Estab #
.*	(2) - Dies it have to be Registered?
•	ACTION TARAN
,	There are a lot of Teople"
1	with a "Lot of Haney" in
•	<u> </u>
	TR was he was attended
	Cabout Enforcement ate, you should
	contact A.F. CARROY (Enforcement)
	- Fir More Into
	Will Do
	RICORDID BY (Name)
	F2 F0M E-5 F0CT, 1988

Form Approved
OMB No. 158 - R006

						OME	<u>No. I</u>	58 - R	0066
U.S. ENVIRONMENTAL PROTECTIO OFFICE OF RESTICIDE PROGRAMS WASHINGTON, D.C. 20080 APPLICATION FOR AMENDED P	(WH-167)	1. Reference cooe	造						
PRODUCT REGISTRATIO		3. REGISTRATION NO.	4. P	RODL		ANAG			
. ■		35900-2	1.	т.	hm T	י די			
(Read instructions on lest page before	e completing)	00000-6		90	tiit I	H. I	.ee		
S. HAME AND ADDRESS OF REGISTRANT finely	de Zip Code)		6-	Ŧ	YPE (OF AM	EHDM	ENT	
_	j.	_	X	CN	AN G E	IN PR	0 000	TNO	-1 E
Γ		7		POI	PMUL.	HANG	Z TH		
Ionics, Incorporated				PE	QUES'	POR	ADDI	YION	AL
P.O. Box 99				RE	OU Es.	Teor	Mark 1	ILLE	
Routes 519 & 50			L	PR	HOTI	CE 70	-1	M PUI	<u> </u>
		061	LETIO	N OF	LAGO	LFE	×Т		
Bridgeville, PA 15	017			AO	OEOU	9 KB (1	vithou	t detaj)
		_	Ĺ	AB	OEOL	HES A	alty q	P2@)	
CHECK HERE IF THE	B IS A NEW ADDRE		X	4 81	NERA	-	THON	OFL	ABE
7. PRODUCT HAME	,		8. E	X PER	IMEH,	TAL P	ERMI	T NO.	
HYgene Mark I Bacteriostat	ic Water Fi	lter Media							
9. SUEJECT OF AMEHOMENT (See Instructions)	Chango pro	disat name from	TTTZ	· -	_ 7~	I			,
Water Wilton Medium to abo	Cueride bro	duct name from	. Ul	gen	ie 13	acte	er10	SCAL	1C
Water Filter Medium to abo	ve (7) produ	ict name. Gene	ral	rev	isic	m o	f la	bel	
to meet current regulations.									
12.			۶۰۰	1			4-4-4		
TYPES OF OATA	TORMITTED		7-4	7 : 8	, POR	I EFA	· 172# (OMLY	•
X at NONE			120 1		T	1	Τ	T	Т
SE PRODUCT CREMISTRY			1202	Т		7.			1
SE REBOUE CHEMISTRY			1808		1	1			1
C4 ENVIRONMENTAL CHEMISTRY			1884	-	 		_		\vdash
DS EFFICACY	 		1208		1.	 			
GS PNYTOTOXICITY		· · · · · · · · · · · · · · · · · · ·	7200		 	 	 	 	
D7 HUMAH SAPSTY			1207		 -	 	├	 	
00 DOMESTIC ANIMAL SAFETY			1204	<u> </u>	 	 		١.	
SE FISH AND WILDLIGE BAFETY			1808		 	 		-	├
10 SENSPIGIAL INSECT SAPETY			1210	: N N /A	Toward.	4. 7/4	4985~	 	
II ACCIDENT EXPOSURS EXPERIENCE			1211	a	 	000			lity
13 OYHER (Specify)			12 18		 		-		
IS OTHER (Specify)			1212	tager	140	-		- No.	-
13. METHOD OF SUPPORT (See (netructions)	14. CONTACT PD	167				ICATI	CN RI	<u> </u>	
Required Supporting Data Attached. (2A) Required Supporting Data is Submitted by References. (2B) Proceed on the Bauis of Eurabitehed-Use	Complete its for identifies to be contac	rms directly below tilon of individual tod, if necessary, als application.			+d)				
OFFER TO FAY STATEMENT	NAME		1						
I hereby offer to pay retsonable compense-	TTT 1L T	T1.m1]						
tion to the extent provided under Section 3	Walter J	. Polens	1						
(c)(1)(D) of the Federal Insecticide, Fungi- cide, and Rodenticide Act, so amended, and	TITLE		1						
n accordance with the Reguletions and	Trice Dwe	~1.1t							
Suidelines published thereunder for use of any test data which has been submitted to	Vice Pre	sident	Į						
the U.S. Environmental Protection Agency in	TELEBHOUE NO	(Include Arco Code)	1						
connection with an application for the regio- tration of a posticide for the first time on or	. SU SPHONE NO.		1						
after October 21, 1972 and which may be	(412) 343	-1040							
Dand in support of the registration amplica- tion for the subject posticide	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	mv AV							
	17. TITLE	<i>&</i>							
The Delice									
Walter J. Polens	6/12/81	•							
PA Fera 8578-17(0\$75)									

-	· •	····			j emnik			Appr No. I	
OFFICE	ONMENTAL PROTECTION OF PESTICIDE PROGRAMS ENINGTON, O.C. 20450	N AGENCY (#16567)	1. REFERENCE CODE	ä				PART.	S
	ON FOR AMENDED P		3. REGISTRATION NO.	2000E	ROOL	ICT M	ANAG	E R	
	octions of lest page before	_	35900-2			ın H	_		
	ESS OF REGISTRANT (Inclus			4.		YPE			
		•		X		ANGE			
F	ios Tonocomon to		٦.		PO	MANUL.	A.T.ION	l	
	ics, Incorporated O. Box 99	1		<u> </u>		90 661	W. C.		
•	utes 519 & 50				IN	OUEET POTION	FOR DEMUL	MUL.	N P
1		:A10				L KT10			L T
l L	idgeville, PA 18	, YLIV				O EO U		*********	
	_		· -		400	0 40 0	MES A	rith d	+s)
	CHECK HERE IF THE	ETE A NEW AGORE	(44 ·	X		HERAL			
7. PRODUCT NAME				4. E	X产售员	IMENT	TAL P	K AMI	TNO
mindene Ms	rk I Bacteriostati	ic water Fi	tter Media						
X OF NONE	TYPES OF DATA		V	1201	$oxed{\bot}$		T EPA	L	L
	CHEMISTRY	· · · · · · · · · · · · · · · · · · ·			-	-	+	1	7
DE PRODUCT		···		1202					
SE RESIDUE O				1202 120E	+		E		上
SE RESIQUE C	NEMIETRY Ental chemietry			120E			Ŀ		
SE RESIQUE C OA ENTIRONM DE EFFICACT	HEMIETRY Ental Chemietry			120E 1268 1208		2			
SE RESIQUE C	HEMIETRY Ental Chemietry Ricity			120E		<i>*</i>			
DE RESIDUE C QA ENTIRONM DE EFFICACT DE FNTTOTOS QT NUMAN EAT	HEMIETRY Ental Chemietry Ricity			120E 1288 1208		2 2			
DE RESIQUE C DA ENTIRONM DE EFFICACY DE FINTTOTOS DO DOMETIC DE FISH AND S	ENTAL CHEMIETRY RICITY PETT ANIMAL SAFETT WILDLIFE EAFETT			120E 120s 120s 120E 120T 120T 120S					
DE RESIQUE CO DA ENTIRONM DE EPPICACY DE PNTTOTOS DO NUMAN EAI DE DOMESTIC DE FISH AND S 10 EENEFICIA	ENEMISTRY ENTAL CHEMISTRY RICITY PETT ANIMAL SAFETY WILDLIPS SAFETY			120E 120S 120S 120E 120T 120E 120S 120S			1450		
DE RESIQUE CO GA ENTIRONM DE EFFICACT OE PHITOTOS GT NUMAN EAT DS DOMRETIC DS FISH AND TO ERNEFICIA IT ACCIDENT	ENEMISTRY ENTAL CHEMISTRY RICITY PRTY ANIMAL SAFETY WILDLIPS SAFETY AL INSECT SAFETY ESPOSURS EXRESSIONS			120E 1208 1208 1206 1207 1208 1208 1219			1480		
DE RESIDUE C OA ENTIRONM DE EFFICACT OE PRITOTOS OF NUMAN EAS OB DOMEETIC OB FISH AND S IS EENEFICIA IT ACCIDENT IZ OTNER (5p)	HEMISTRY ENTAL CHEMISTRY RICITY PRTY ANIMAL PAPETY WILDLIPE SAPETY AL INSECT BAPETY ESPOSURE EXHERISNOS OCTOP			120E 1208 1208 120E 120T 120E 120E 1212 1212			### # 144*		
DE RESIDUE C QA ENTIRONM DE EFFICACY QE PHYTOTOS GY NUMAN EAT DO DOMEETIC DE FISH AND TO TO EENEFICIA IT ACCIDENT 12 OTHER (Sp.	HEMISTRY ENTAL CHEMISTRY RICITY PRTY ANIMAL PAPETY WILDLIPE SAPETY AL INSECT BAPETY ESPOSURE EXHERISNOS OCTOP	I4. GONTACT PO	DINT	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			
DE RESIDUE C QA ENTIRONM DE EPPICACT OE PNTYOTOS QT NUMAN EAI DS DOMEETIC OB PISH AND S TO EENEPICIA TO ACCIOENT TO OTHER (Sp.	ENTAL CHEMIETRY ENTAL CHEMIETRY KICITY PETT ANIMAL SAFETY MILDLIFE EAFETY AL INEECT SAFETY ESPOSURE EXRERENCE ocify) PORT (See instructions) wring Data Attached. (2A) orting Date is Submitted (2B)	Complete in for identific to be contact to process ti	ema directly below gited, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			
DE RESIDUE C QA ENTIRONM DE EFFICACY OE FINTTOTO OF NUMAN EAI OB DOMESTIC OB FISH AND II II EENEFICIA II ACCIOENT II OTHER (Sp. II	ENTAL CHEMIETRY ENTAL CHEMIETRY SICITY PETT ANIMAL SAFETT WILDLIFE EAFETT AL INEECT SAFETY ESFOSURE EXRERIENCE ocify) FORT (See Instructions) wring Data Attached, (2A) orting Data Attached, (2A) PAY STATEMENT resecreble compenses	Complete its for identificate to be contact to process its NANE	ema directly below Etion of individual ted, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			
DE RESIDUE C OA ENTIRONM DE EFFICACY DE FNYTOTOS OF NUMAN EAS DO DOMETIC DE FISH AND S SO CHER (Sp. SO CHER	ENTAL CHEMIETRY ENTAL CHEMIETRY ELICITY PETT ANIMAL SAFETT AL INEECT BAFETY EXPOSURE EXHERIENCE ocify) PORT (See instructions) wring Data Attached. (7A) orting Data Attached. (7A) orting Data Submitted (2B) FAY STATEMENT residenthic companes trail insecticids. Fungi-	Complete in for identificate to process if	ema directly below Etion of individual ted, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			3
DE RESIDUE C QA ENTIRONM DE EFFICACY OE FINTTOTOS OF NUMAN EAR OB DOMESTIC DE FISH AND TO THE ACCIONY 12 OTHER (Sp. 12 OTHER (Sp. 13. METNOD OF SUPILIFIED S	ENTAL CHEMIETRY ENTAL CHEMIETRY ELITY PETT ANIMAL SAFETT MILDLIPE EAFETT AL INEECT BAFETY ESPOSURE EXRERIENCE ocify) PORT (See Instructions) wring Date Attached, (2A) orting Date is Submitted (2B) FAY STATEMENT reseonable compensa- ovided under Sections tral Insecticids, Fungi- is Act, EE amended, and her Resentations and	Complete in for identific to be contact to process to wante. Walter J	ems directly below cition of individual cited, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			
DE RESIDUE C OA ENTIRONM DE EFFICACT OE FINT TOTO: OF PINT TOTO: OF NUMAN EAR DE BOMRETIC OB FISH AND: ID EENEFICIA IT ACCIOENT IZ OTHER (Sp.	ENTAL CHEMIETRY ENTAL CHEMIETRY ELCITY PETT ANIMAL SAFETT WILDLIFE EAFETT AL INEECT BAFETY EAPODURE EXHERIENCE ocify) PORT (See Instructions) wring Data Attached. (2A) octing Date is Submitted (2B) FAY STATEMENT resconsible compenses ovided under Sections of the bean submitted in the formula of the formula of the formula of the bean submitted in the formula of the bean submitted in the formula of the bean submitted in the control of the bean submitted in the control of the bean submitted in the control of the bean submitted in the control of the control o	Complete in for identificate to process if	ems directly below cition of individual cited, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			
DE RESIDUE C QA ENTIRONM DE EFFICACY OE FINTTOTO OF NUMAN EAR OB DOMESTIC OB FISH AND IT TO EENEFICIA IT ACCIOENT IZ OTHER (Sp. IZ	ENTAL CHEMIETRY ENTAL CHEMIETRY ELITY PETT ANIMAL SAFETT WILDLIFE EAFETT AL INEECT SAFETY EMPOSURE EXHERIENCE ocity) PORT (See Instructions) wring Date Attached, (2A) orting Date Attached, (2A)	Complete in for identific to be contact to process to p	ems directly below cition of individual cited, if necessary, his application.	120E 120S 120S 120S 120E 120F 120S 120S 121S 121S 121S 121S 121S		APPL			3
DE RESIDUE C OA ENTIRONM DE EFFICACT OE FITTOTO OF PITTOTO OF NUMAN EAR OB DOMETIC OB FISH AND I ID EENEFICIA IT ACCIOENT IZ OTHER (Sp. IZ OTHER (SP. IZ OTHER (SP. IZ OTHER (SP. IZ OTHER (SP. IZ OTHER (SP. IZ OT	ENTAL CHEMIETRY ENTAL CHEMIETRY ENTAL CHEMIETRY FETY ANIMAL SAFETY ALINEKCT SAFETY ESPOSURE EXHERITHACE ecily) PORT (See instructions) wring Data Attached, (2A) orting Data Attached, (2A) orting Data Attached, (2A) error of washing data for the fine companies for the fine time on or 72 and which hay be se registrating applica- for the finet time on or 72 and which hay be se registrating applica-	Complete in for identificate to process to p	ems directly below stion of individual sted, if necessary, his application. Polens esident	120E 120S 120S 120S 120E 120F 120F 120S 121S 121S 121S 121S		APPL			
DE RESIDUE C OA ENTIRONM DE EFFICACY OE FITTOTO OF PITTOTO OF NUMAN EAR OB DOMETIC OB FISH AND I IS EENEFICIA IT ACCIOENT IZ OTHER (Sp. IZ OT	ENTAL CHEMIETRY ENTAL CHEMIETRY ENTAL CHEMIETRY FETY ANIMAL SAFETY ALINEKCT SAFETY ESPOSURE EXHERITHACE ecily) PORT (See instructions) wring Data Attached, (2A) orting Data Attached, (2A) orting Data Attached, (2A) error of washing data for the fine companies for the fine time on or 72 and which hay be se registrating applica- for the finet time on or 72 and which hay be se registrating applica-	Complete in for identificing be contact to proceed it. NAME Walter J VICE Pre TELEPHONE NO. (412) 343	ems directly below stion of individual sted, if necessary, his application. Polens esident	120E 120S 120S 120S 120E 120F 120F 120S 121S 121S 121S 121S		APPL			

#

Posm Approved
OMB No. 158-R0066

U.S. ENVIRONMENTAL PROTECTION OFFICE OF PESTICIDE PROGRAMS WASHINGTON, O.C. 20466 APPLICATION FOR AMENDED P PRODUCT REGISTRATION	(#B-547) ESTICIDE	1. REFERENCE CODE 2. REGISTRATION HO.	4.78	GOUGT	MANAG	7	
(Read instructions on last page before		35900-2	Jo	ohn F	I. Le	e	
L HAME AND ADDRESS OF REGISTRANT (Inclus		<u> </u>	14.	TYPE	OF AMI	EN DHEN	т
		7 .	X	THURST	CRASS	9 BUCT !	IAME
Ionics, Incorporated P.O. Box 99	1			PRANC	NAMEL	ADDITIO	
Routes 519 & 50				HEGUE PREGUE	PORMUL FICE 74.	MULTIP ATTON !	FER
Bridgeville, PA 18	5017	ſ				Tibout 4	
			v.			rith date	
CHECK HERE IP THI	1 18 A 4E# AUUK!		L'A			ERMIT N	
HYgene Mark I Bacterios	tatic Water	Filter Media					
Bacteriostatic Water Filter revision of label to meet cu	Medium to	product name above (7) prod ations.	luct r	ame	. Ge	-	
TYPER OF DATA		14 T	100		e y		
X 81 HONE			1201		in Archi		1. L.S.
DE PRODUCT CHEMISTRY			1205				
DA ENVIRONMENTAL CHEMISTRY			1204		en de la companya de la companya de la companya de la companya de la companya de la companya de la companya de La companya de la companya de la companya de la companya de la companya de la companya de la companya de la co	37 30 X	an and
48 EFFICACY		<u> </u>	1965			22	7. P. 19.
OS PHYTOTOXICITY			1200			Subjective (24 CK.
07 HUMAN SAPETY			1107	62 33	() ME	Servi E	949 YZ
08 DOMESTIC ANIMAL SAPETY			1200	Same Same	un k ilon it	1000° 3	74 . 12 200
OS FISH AND WEDLIFE SAFETY			1205		(d. 2048)	2 ~ 1	995 B
18 SENEFICIAL INSECT SAPETY			1810	A 7 7 2 2	e es		
IL ACCOUNT EXPOSURE EXPERIENCE			1217		Our Browning		
18 GTHER (Speelly)		-	1812			500 and 500	
11. METHOD OF SUPPORT (See instructions)	IA, CONTACT PO	SINT		TE AP	LICATI	ON AKC	DVED
Required Supporting Data Attached. (2A) Required Supporting Data is Submitted by Reference. (2B) Proceed to the Scott of Submitted Sur- Retinant. (2C).	(or identifie to be contac to process t	ems directly below atten of individual ited, if secessary, his application.	, 34 	(
OFFER TO FAY STATEMENT I hereby offer to pay reasonable compensa- tion to the extent provided under Section 3 (c)(1)(D) of the Federal Insectining Function		J. Polens		•			
cide, and Rodenticide Act, an embaded, and in accordance with the Regulations and Guidelines published thereunder for use of any test date which his been mimitted to the U.S. Reviewsment Reptection Agency in	Vice Pr						
connection will an applicablen for the regis- tration of a sentimide for the first time on or other Copster 21, 1972 and which may be used in support of the registration applica- tion for the subject postings.	(412) 34	(San Sudo Area Cado)					
ia signatura	17. YIYCK	R.		,	•		
Walter J. Polens	6/12/81	Ĺ.					
EPA Perm (879-11 (1-75)			· · · · · · · · · · · · · · · · · · ·				

3 3



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5105973299

June 10, 1981

Mr. John H. Lee, Product Manager 31
Disinfectants Branch
Registration Division (TS-767)
U. S. Environmental Protection Agency
401 M Street S. W.
Washington, D. C. 20460

SUBJECT: Application for Amended Pesticide Product Registration for Registration No. 35900-2

Dear Mr. Lee:

Enclosed with this letter you will find our "Application for Amended Pesticide Product Registration", your Form 8570-11. The amendment is because of change of product name from HYgene Bacteriostatic Water Filter Media to HYgene Mark I Bacteriostatic Water Filter Media. General revisions of label also to meet current regulations. We have also enclosed your Form 8570-4 "Confidential Statement of Formula" along with five final printed labels. Five copies of our revised Product Data Sheet are enclosed which show these changes.

This change does not affect the efficacy and safety of use of this product.

Your early consideration of this amended registration will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED

Walter J. Polens

Vice President

WJP:mle

Enclosures

HYgene Mark I

BACTERIOSTATIC WATER FILTER MEDIA

Removes objectionable tastes, odors, color from treated municipally— supplied tap water.
Inhibits the growth of bacteria within the filter

media bed.

CAUTION: KEEP OUT OF REACH OF CHILDREN COLOR EPA Reg. No. 35900 - 2 EPA Est. No. 35900 PA. Ol.

ACTIVE INGREDIENT

SILVER as Ag NO₃ ---- 1.05 % LOT No._____

INERT INGREDIENT

ACTIVATED CARBON---98.95 % NET CONTENTS_____cu.ft.

STORAGE ---- Store In closed container which excludes moisture and fumes.

DIRECTIONS FOR USE---- Refer to enclosed product data sheet.

DISPOSAL OF SPENT MEDIA --- Retain Shipping carton and liner for disposing of exhausted filter media with trash.

USE----- This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

, IONICS, INC. Routes 519 & 50 P.O.Box 99 Bridgeville, Pa. 15017 🕏

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA PRODUCT DATA

DIRECTIONS FOR USE GENERALCLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO₃) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING |

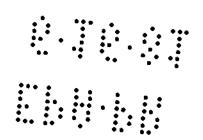
6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT

Bridgeville, Pennsylvania





P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Eacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during non-flow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side



P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are pmparable to those of granular activated carbon, upon which a silver coating has been eposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacterio-static agent in Hygene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during nonflow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

<u>DIRECTIONS FOR USE</u> GENERALCLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as $AgNO_3$) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

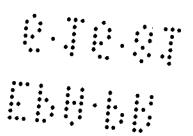
PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT



<u>DIRECTIONS FOR USE</u> GENERALCLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO₃) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

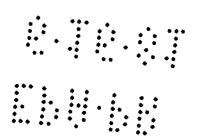
PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT





P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are comparable to those of granular activated carbon, upon which a silver coating has been eposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacteriostatic agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during nonflow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

HYgene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

<u>DIRECTIONS FOR USE</u> GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Hygene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

<u>INGREDIENTS</u>

ACTIVE INGREDIENT

Silver (as $AgNO_3$) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

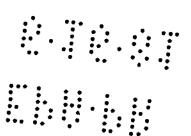
PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT





P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are emparable to those of granular activated carbon, upon which a silver coating has been eposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

Silver, which has been chemically plated onto the activated carbon, is the Bacterio-static agent in HYgene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during nonflow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

Hygene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.

See Reverse Side

<u>DIRECTIONS FOR USE</u> GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS_

INGREDIENTS

ACTIVE INGREDIENT

Silver (as $AgNO_3$) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

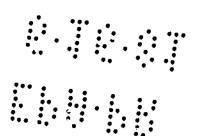
PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT



DIRECTIONS FOR USE GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as $AgNO_3$) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT





P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017

HYGENE MARK I Bacteriostatic Water Filter Media

HYGENE MARK I BACTERIOSTATIC WATER FILTER MEDIA

- . Removes objectionable tastes, odors, and color from treated municipally supplied tap water
- . Inhibits the growth of bacteria within the filter media bed

WHAT IT IS AND HOW IT WORKS

The physical characteristics of HYgene Mark I Bacteriostatic Water Filter Media are emparable to those of granular activated carbon, upon which a silver coating has been eposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver, and also to perform the usual functions of an activated carbon filter media by removing the many impurities often found in potable water supplies such as turbidity, suspended solids, chlorine, and objectionable tastes and odors.

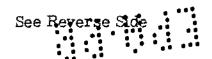
Silver, which has been chemically plated onto the activated carbon, is the Bacterio-static agent in Hygene Mark I Bacteriostatic Water Filter Media. A Bacteriostatic Filter Media is one which will inhibit the growth of bacteria within the filter bed.

Since "potable" water can, by law, contain a certain number of harmless bacteria indigenous to municipally treated water, the potential for a build-up or growth of these bacteria trapped within the filtering medium does exist.

The low level of bacteria in tap water along with organic compounds normally present in a water supply become trapped in the filter bed medium. After a period of time, the filter bed will contain considerable number of bacteria and in the presence of the organic compounds, which becomes a source of nutrients for bacteria, this filter becomes a breeding place for bacterial growth especially during nonflow periods when the water is not in use, such as overnight.

WHO MAY USE THIS PRODUCT

Hygene Mark I Bacteriostatic Water Filter Media is to be used only for manufacturing or fabricating bacteriostatic water filter products for home use. Filter manufacturers or formulators who use this media are responsible for providing data to the United States Environmental Protection Agency to support the registration of their products.



<u>DIRECTIONS FOR USE</u> GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as AgNO₃) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT



<u>DIRECTIONS FOR USE</u> GENERAL CLASSIFICATION

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

HYgene Mark I Bacteriostatic Water Filter Media requires an initial rinse before use to remove excess carbon fines and entrapped air. This rinse rate should be proportionate to a bed of 0.25 lb. media, at a flow rate of 0.5 gpm for 15 minutes. Following this initial rinse, the inservice flow rate is not to exceed 15 gpm per cu. ft. of media. Bed depth must be at least twice the diameter.

SPECIFICATIONS

INGREDIENTS

ACTIVE INGREDIENT

Silver (as $AgNO_3$) - 1.05%

INERT INGREDIENT

Activated Carbon - 98.95%

STORAGE

Store in closed container which excludes moisture and chemical fumes.

MESH SIZE

12 x 30 U.S. Sieve Series

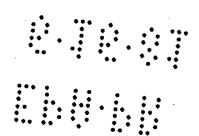
PACKAGING

6 Cu. Ft. Fiber Drums 1 Cu. Ft. Carbon

WEIGHT

30 Lb. Per Cubic Foot

SHIPPING POINT



Г			1.	REGISTRATION NUM	BER	CYCLE	2, D4	ATE RECE	IVED
	SUB	MISSION REVIEW RECORD G	359	10-	1 5		C'S	dő	719
3.	3CID	PUBLICATION NECESSARY	4. PETITION	V NO.			5. REC	EIVED PM	TEAM
		YES NO					08	71	29
€.	MET	HOD OF SUPPORT	7. PRODUC	T MANAGER		ND.	S, PROJ	ECTED A	ETURN
		2A		Lec		3/	MD	DAY	YR
9.0	BTAC	PULLED 10 DATE PUBLISHED	11 ACTION	TAbe		CODE	12. OUT	GOING D	ATE
				2006		51	MO 	DAY	YR
. .	≱ ₩ ₁₁₁ 111		REVIEWER]		COM-	DATER	EVIEW CO	MPLETED
SEQ.	REVIE TYPE CODE	REVIEW TYPE	CODE (Initials)	SIGNATURE OF	REVIEWER	MENT	Mo	DAY	ΥR
	A	REVIEWABILITY TEAM		*					
	В	PRODUCT MANAGER TEAM EFFICACY REVIEW	***************************************	ļ	<u></u>				
	С	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW							
	D	PRODUCT MANAGER TEAM EN- YIRONMENTAL SAFETY REVIEW							
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	[6'D	K Do	9/95,	NEN	08	21	29
	F	PRODUCT MANAGER							
	G	INTERAGENCY REFERRAL							
ļ	Н	COST-BENEFIT REVIEW							
_	1	PUBLIC COMMENTS REVIEW							
	J	REE BRANCH INSECTICIDE EFFICACY							
	К	EEE BRANCH HERBICIDE EFFICACY					1		
<u> </u>	L	EEE BRANCH FUNGICIDE EFFICACY							
	М	EEE BRANCH RDDENTICIDE EFFICACY							
<u> </u>	N	EEE BRANCH DISINFECTANT EPFICACY					1		
_	0	CHEMISTRY BRANCH RESIDUE CHEMISTRY							
	P	EEE BRANCH ENVIRON . MENTAL CHEMISTRY							
	Q	TOXICOLOGY BRANCH HUMAN SAFETY							
	R	SEE BRANCH ENVIRON- MENTAL SAPETY							
	s				·				
	Т			TVDE AF BERBAURF					SODE -
PAC	DUC	T MANAGER SIGNATURE		Type of Response				<u>-</u>	CODE



July 30, 1979



Dear

This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

We would be pleased to allow the EPA to refer to this data in our files but not to show this to you as this is proprietary information and classified "Confidential". We would, however, agree that since

We look forward to receiving your reply.

Very truly yours,

IONICS, INCORPORATED

Walter J. Polens Vice President

WJP:mle

cc: J. D. Collins - Ionics

E. Brown - EPA

J. Banks - EPA

J. Lee - EPA





July 30, 1979



Dear

This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

We would be pleased to allow the EPA to refer to this data in our files but not to show this to you as this is proprietary information and classified "Confidential". We would, however, agree that since



We look forward to receiving your reply.

Very truly yours,

IONICS, INCORPORATED

Walter J. Polens Vice President

WJP:mle

cc: J. D. Collins - Ionics

E. Brown - EPA

J. Banks - EPA

J. Lee - EPA



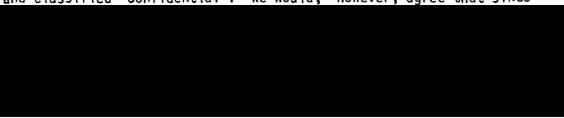
July 30, 1979



Dear

This letter will confirm our telephone conversation of July 30th in reference to your offer to commence negotiations to determine compensation for using the data in our files under EPA Reg. No. 35900-2 to register your water filter under the Federal Insecticide/Fungicide/Rodenticide Act.

We would be pleased to allow the EPA to refer to this data in our files but not to show this to you as this is proprietary information and classified "Confidential". We would, however, agree that since



We look forward to receiving your reply.

Very truly yours,

IONICS, INCORPORATED

Walter J. Polens Vice President

WJP:mle

cc: J. D. Collins - Ionics

E. Brown - EPA

J. Banks - EPA

J. Lee - EPA

ENFORCEMENT CASE REVIEW	
To: Director, Pesticides Enforcement Division	1.D. NO. 131823
Office of Enforcement and General Counsel	EPA REGISTRATION NO. 35900-2
PRODUCT NAME (On sample label)	35900-2
BON DEL BACTERIOSTATIC WATER FILITER	
COMPANY NAME AND ADDRESS (On eample label) (Include ZIP code)	REGISTRATION STATUS AT TIME OF
Bon Del, Inc.	SHIPMENT * X REGISTERED
2605 East Geneva Drive Tempe, AZ 85282	NOT REGISTERED
OISTRIBUTOR STATUS AT TIME OF SHIPMENT ((f epplicable)
BASIC PRODUCT NAME	PRODUCT SUPPLEMENTALLY
	REGISTERED
HYGENE	T YES & NO
SISTRANT HAME AND ADDRESS (Include ZIP code)	DATE OF SUPPLEMENTAL REGISTRATION
Lonics, Inc.	To average the second s
P.O. Box 99 Bridgeville, PA 15017	
OTHER PERTINENT REGISTRATION DATA	
A company number has not been assigned to Bon Del In Tempe AZ 85282. The filter is registered. However, the three models and Refrigerator) are not registered.	·
IS THIS A PESTICIDE? YES (II you, flet claims below) NO	
PESTICIDE CLAIMS	
SIGNATURE OF BRANCH CHIEF (Registration Div., Oilice of Positions Programs) Edward L. Bunch Enforcement Coordinator - Registration	S/15/79

	ID NUMBER
ENFORCEMENT CASE REVIEW	131823
(Test and Label)	EPA REGISTRATION NUMBER
	NONE
	TYPE OF REVIEW
CHEMISTRY EFFICACY SAFETY	Y OTHER (Specify)
TEST RESULTS AND SIGNIFICANCE	
1. no directions to assume ?	he adopte we of the types of water when top model", "protable model"
felton, edentified as Co	mater top model , portable model
and refrgention motal, w	we included in the sample labeleys.
2. The posticidal claim	"dostroya all botheric sheards the
The second of th	The American Control of the Control
- water faller made,	yen", we monted in the water
3. The collection to come	"medical Tolore " good a false."
last 1 the moderate was	Whe affective in Siminating polletonts
ARE THERE ANY SIGNIFICANT LABELING DEFECTS?	LABELING REVIEW DATE OF ACCEPTANCE OF APPLICABLE LABELING
YES (If yes, list substantial discrepancies and sig	
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES	1/30/79
I from arriking water	· · · · · · · · · · · · · · · · · · ·
	Dh Porter
	De Porter Di
i	·
[;
<u> </u>	
}	
i	
,	
ļ	
1	

	RCEMENT CASE	REVIEW	131823	
WHIC	(Test and Label)	EPA REGISTRATION NUMBER	R
		778E	35900-2	
CHEMISTRY	LEFFICACY	SAFETY	OTHER (Specify)	
· [1"1	154	<u> </u>	
ESI KESULIS AND	1 31GHT TONICE	Â	Landys,	La Commence Commence
The w	asatal	Charecen	K morthon	Jacumeny
* * **				
2 March				
•				
ŝ				
7				
			ING REVIEW	
RE THERE ANY SIG	SHIFICANT LABELING		ING REVIEW	DATE OF ACCEPTANCE APPLICABLE LABELING
				DATE OF ACCEPTANCE APPLICABLE LABELING
YES (II YOU	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
YES (II YOU	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
YES (II YOU	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
YES (II YOU	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
YES (II YOU	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
ESTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
ESTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	APPLICABLE LABELING
ESTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	below)	10/29/15
ESTANTIAL DISCR	, liet eubelantiet diecre	3 DEFECTS1 pancies and significance IFICANCES	retty toch	Ino 10/29/15
ESTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	retty toch	Ino 10/29/15
YES (II YOU BSTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	rely forts	Ino 10/29/15
ESTANTIAL DISCR	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	rely forts	Ino 10/29/15
YES (II YOU	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	retty toch	Ino 10/29/15
PES (II you	Het eubelantial diecre	3 DEFECTS1 pancies and significance IFICANCES	rely forts	Ino 10/29/15
JESTANTIAL DISCF	REPANCIES AND SIGNI	B DEFECTS1 prencise and significances FICANCES	rely forts	Ino 10/29/15
JESTANTIAL DISCF	REPANCIES AND SIGNI	B DEFECTS1 prencise and significances FICANCES	rely forts	Ino 10/29/15
VES (II you	Het eubelantial diecre	B DEFECTS1 prencise and significances FICANCES	rely forts	Ino 10/29/15

, ENFORCEMENT CASE RE	EVIEW
To: Director, Pesticides Enforcement Division	I.D. NO. EC-79-28
Office of Enforcement and General Counsel	EPA REGISTRATION NO. 35900-2
PRODUCT NAME (On sample label)	
BON DEL HARTERIOSTATIC WATER UNIT	
COMPANY NAME AND ADDRESS (On sample label) (Include ZIP code)	REGISTRATION STATUS AT TIME OF
Bon Dal, Inc.	REGISTERED
2605 East Geneva Drive Tempe, AZ 85282	NOT REGISTERED
DISTRIBUTOR STATUS AT TIME OF SHIPM	MENT (If applicable)
BASIC PRODUCT NAME	PRODUCT SUPPLEMENTALLY REGISTERED
насеме	TES (X) NO
5'. RANT NAME AND ADORESS (Include ZIP code)	DATE OF SUPPLEMENTAL REGISTRATION
Icaics, Inc. P.O. Box 99	
Bridgeville, PA 15017	
OTHER PERTINENT REGISTRATION DATA	
IS THIS A PESTICIDE? SYES (If yee, fiet claims below) NO	
PESTICIDE CLAIMS	
Bernell	
SIGNATURE OF BRANCH CHIEF (Registration Div., Office of Posticides Programs) Enforcement Coordinator - Registration	5-31-79

	***			111	D NUMB	ER Z		79-	- 2	F		
ENFO	RCEMEN (Test a	T CASE R nd Label)	EALEM	E	EPA REC	ISTRATIO						
	,					25	90	00 -				
			.,.	TYPE OF								
EHEMISTRY	EFF.	ICACY	SAFET	٧	אדס	ER (Spacily	")					
EST RESULTS AND	SIGNIFICA	NCE										
)			in pl	,								
				LABELING	REVIE	W						
				· <u> </u>		W			O	ATE OF AC	E LABE	LING
TE THERE ANY SIG				· <u> </u>		M		NC	_ A	PPLICABL	E LABE	LING
Y E\$ (!! 900,	liei aubere	ntial discrep	ancies and sig	· <u> </u>		W		No	_ A	ATE OF AC	E LABE	LING
Y E\$ (!! 900,	llei aubere	ntial discrep	ancies and sig	· <u> </u>		N CONTRACTOR OF THE PARTY OF TH		No	_ A	PPLICABL	E LABE	LING
Y E\$ (!! 900,	llei aubere	ntial discrep	ancies and sig	· <u> </u>		W		NO	_ A	PPLICABL	E LABE	LING
Y E\$ (II yos,	llei aubere	ntial discrep	ancies and sig	· <u> </u>		N CONTRACTOR OF THE PARTY OF TH		NO	_ A	PPLICABL	E LABE	LING
YES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	ancies and sig	initicances ba	TIOW)	ng-yes <mark>.^{Ma}didalinani</mark>			_ A	PPLICABL	E LABE	LING
YES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	ng-yes <mark>.^{Ma}didalinani</mark>				PPLICABL	E LABE	LING
YES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	en e	eng.nq. d-a			PPLICABL	E LABE	LING
VES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	Share from the share of the sha	eng.nq. d-a			PPLICABL	E LABE	LING
VES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	en e	eng.nq. d-a			PPLICABL	E LABE	LING
YES (II YOU, BSTANTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	en e	eng.nq. d-a			PPLICABL	E LABE	LING
BSTARTIAL DISCR	liei aubere	AND SIGHT	encise and sig	initicances ba	rion)	en e	eng.nq. d-a			PPLICABL	E LABE	LING

	ID NUMBER
ENFORCEMENT CASE REVIEW	EC 79-25 EPA REGISTRATION NUMBER
(Test and Label)	\ _
* \D. A.	None_
	F REV性製 OTHER (Spacify)
CHEMISTRY EFFICACY SAFETY	
TEST RESULTS AND SIGNIFICANCE	A
The following claims on the tale	along we considered under the
sovienia vidicated in Section	on 162,10 (a) (5) of the Regulations
for Enforcement of FIFRA as for	las and musicolony Teterants:
I the nesticidal dama for	disinfecting water and killing
with bouters would be affected	chronisa of the action. They were
votability mades "Hygon", ne	orporated in this water tractment devices
3 The mon-pushed down	a for summered of "Insecticules such
as lither two 4. Tolaphort	Industrial Tables
1. Ocatorde on one 11.70	ropylore allowayer They
bandon water see	das 2. arone 11.5. horang week
the state of the same of the latter of	and how such peoplesses.
The week of the state of the st	1-1-1-1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
3. 18. 4 / 11. in this model addition	
LABELL	to deview
LABELII ARE THERE ANY SIGNIFICANT LABELING DEFECTS?	G REVIEW
LABELII ARE THERE ANY SIGNIFICANT LABELING DEFECTS? YES (If yes, fist substantial discrepancies and significances)	Las 2. answer 11. 5. Marcung was rota for peak purposes. (GREVIEW DETAIL OF ACCEPTANCE DE APPLICABLE LABELING NO
YES (If you, flat substantial discrepancies and significances	below) NO APPLICABLE LABELING
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES As be approved by the Environ	montal Protection agency (EPA 74
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) impole a recommon	annutal Protection agency (EPA 74)
YES (11 yes, 11st substantial discrepancies and significances SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) impalies recommons 4 Osticles from Sand House	solow) NO APPLICABLE LABELING AMOUNT OF Endown (EPA 74 Endown or Endown of EPA. Engring, Empire, Property Stagette,
YES (II you, II of outstantial discrepancies and significances SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Par ben approved by the Environ 35400-2) impalies recommons 4 Orticles from Sand House Massa Tribune and other new	solow) NO NO APPLICABLE LABELING APPLICABLE LABELI
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) implies recommons 4 Orticles from the House Mass Tribune and other new the sample holding, quietle	mental Protection agency (EPA # extrem or endorsons of EPA. Engring, Empire, Phoenix tray the speggers, which accompanyed las or misleading improssion
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) impoles recommon 4 Orticles from Good House mass Tribune and other new the sample labeling, grieafe	solow) NO APPLICABLE LABELHAG APPLICABLE LABELHAG APPLICABLE LABELHAG APPLICABLE LABELHAG APPLICABLE LABELHAG APPLICABLE LABELHAG APPLICABLE LABELHAG Expring, Empire Procenia Stagette Appendix or mislending improssion agle product will be affective
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) implies recommons 4 Orticles from the House The sample beloting, grisafe to the purchaser that the same in elementaries the problem	solow) NO APPLICABLE LABELHAGE MODELLA COMPANY Expring, Empire, Phoenix tray the speggers, which occompanyed lac or misleading improssion ple product will be affective to from drinking water.
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ber approved by the Environ 35400-2) impoles recommon 4 Orticles from Sund House mesa Tribune and other ren the sample labeling, grieafo to the purchases that the sam in climinating the polluta- 5. The sample label bears The	APPLICABLE LABELHAGE APPLICABLE LABELHAGE
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) implies recommond 4 Orticles from the House The sample belowing, grisafe to the purchaser that the sam in climinating the polluta 5. The sample ball bears the the water of the media ward in	APPLICABLE LABELHAGE APPLICABLE LABELHAGE
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ber approved by the Environ 35400-2) impoles recommon 4 Orticles from Sund House mesa Tribune and other ren the sample labeling, grieafo to the purchases that the sam in climinating the polluta- 5. The sample label bears The	APPLICABLE LABELHAGE APPLICABLE LABELHAGE
SUBSTANTIAL DISCREPANCIES AND SIGNIFICANCES Las ben approved by the Environ 35400-2) implies recommond 4 Orticles from the House The sample belowing, grisafe to the purchaser that the sam in climinating the polluta 5. The sample ball bears the the water of the media ward in	mental Protection agency (EPA # extron or endormons - by EPA. Engring, Empire, Phoenix tray the spegmen, which occurpanyed lase or misleading improssion ple product will be affective to from drinking water, EPA Registration much for the device, but no EPA Registration



January 13, 1977

Mr. E. F. Brown Chief, Disinfectants Branch Registration Division (WH-567) U. S. Environmental Protection Agency 401 M Street S. W. Washington, D. C. 20460

Dear Mr. Brown:

This letter will authorize you to use any information that is in Ionics, Incorporated's file, our EPA Registration 35900-2, to support registration of additional products for

This letter does not, however, allow you to make public to or anyone else any information in our file that would be considered proprietary information or confidential.

We thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

cc: <u>James H. Banks - EPA</u>

J. D. Collins - Ionics

Please place in EPA Reg No. 35900-2

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Dear Fr. Polens:

This is to acknowledge receipt of your letter of June 22, 1976 regarding the Volhard Method of Amalysis. According to your letter it is our undermanding that the Atomic Absorption Method of Analysis is being used by you or your agent(s) to analyze the "Hypene Racteriostatic Water Filter Media" for silver content rather than the Volhard Method of Analysis. If our understanding of this matter is incorrect, please correct us.

Sincercly,

James H. Banks Product Manager 33 Disinfectants Branch Registration Division (WH-567)

WH-567:DIS:RGD:md:59040:Rm 321 12/17/76

35900-2



P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A.C. 412 343-1040 TWX 5106973299

June 22, 1976

Mr. James H. Banks, Product Manager 33 Disinfectants Branch (WH-567) Registration Division U. S. Environmental Protection Agency 401 M Street S. W. Washington, D. C. 20460

SUBJECT: Volhard Method of Analysis

Dear Mr. Banks:

This is in reply to your letter of June 1, 1976 in reference to the Volhard Method for the determination of silver.

Silver Analyses in conjunction with our Hygene product testing for EPA are run at NUS Corporation, Cyrus Wm. Rice Division. We have been advised by Mrs. Linda Deans, Manager of Analytical Services at NUS that the Volkard Method is not presently being used in their laboratory for silver analysis. According to Mrs. Deans and several other reliable sources we have contacted concerning this subject, the Atomic Absorption Method is considered much more accurate than the Volkard Method not only in the trace quantity (ppb) range but also in the high silver concentration (ppm) range.

If there are any further questions in this regard, please advise us.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

cc: J. O. Collins - Ionics

REGISTRATION DIVISION

JUN 01 TE

IONICS, INC. Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Gentlemen:

Subject :

LETTER OF May 11, 1976

The information submitted with your letter of May 11, 1976 regarding the Atomic Absorption Method of Analysis is acceptable. However, in order to satisfy the general chemistry data requirements, you must submit details of the Volhard Method of Analysis as also requested in our letter of April 28, 1976.

Sincerely,

James H. Banks
Product Manager 33
Disinfectants Branch (WH-567)

WH-567: DIS: RGD: md: 59040: Rm 321 5/28/76



May 11, 1976

Mr. James H. Banks, Product Manager 33 United States Environmental Protection Agency Disinfectants Branch (WH-567) Registration Division 401 M Street S. W. Washington, D. C. 20640

Ref: Your Letter Stamped April 28, 1976

Dear Mr. Banks:

Enclosed with this letter is a copy of a letter we received from NUS Corporation which gives the details of the Atomic Absorption Method of Analysis. This should satisfy your general chemistry data that you requested.

I appreciate receiving the information on the progress of our submission of December 5, 1975 in reference to Pool Gene and we will look forward to receiving the completed report within the next few weeks.

I have also enclosed with this letter a copy of my letter of February 18, 1976 in which I requested status on our Food Additive Petition No. 5H5079. I have heard nothing at all about this. I would appreciate a reply as soon as possible.

Thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosures (2)



February 18, 1976

Mr. James H. Banks. Product Manager 33
United States Environmental Protection Agency
Disinfectants Branch (WH-567)
Registration Division
401 M Street S.W.
Washington, D. C. 20640

Dear Mr. Danks:

Would you please inform me of the status of our Food Additive Petition No. 5H5079 which was sent to you on February 10, 1975 and which you informed us was being filed on March 27, 1975.

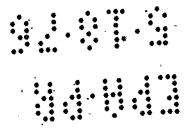
Your prompt attention to the above will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle



Γ				1.	94 jil		REGIS	TRATI	ON NU	18ER		:::::: :::::::::::::::::::::::::::::::	CYCL€	2.	0/	\TE (RECE	IVE	D
		MISSION	REVIEW RECORD G		5	9	0	/ -	<u>```</u>		4	2			B	2	ĵ9	7	6
3.	3 C1D	PUBLICA	TION NECESSARY	4.	PET	ITION	NO.	.:	. %.			÷				····		4 TE/	
		Y E S	No						. 4			s fr Till i		:	1	ם	AY	,	/R
6,	MET	HOO OF S	UPPORT	7.	PRO	puç	MAN	AGER				€£ .	NO.	8.	PROJ	ECT	ED P	ETU	RN
		2 A] 28	<i>*</i>	η (1	500	r L	5				33		ио 	D	^	`	/R
9.	OATE	PULLEO	10, DATE PUBLISHED	11.	ACT	~	TYPE		:				COOE	12.	οyτ	9011	·97	AIF	20
					K	2	S a	Br	715	510 r	\		5/		18	PA	1	Ź	6
مٰ ح	ani ¥		REVIEW TYPE		VIEV		:: g	IGNAT	TURE O	FREV	IEWER		COM- MENT	D/	ATE P	EVIE	w co	WPLE	TED
REV SEQ.	REVIE CODE				Initia							á:	COOE	,	40	D	AY		YR
Ľ	A	REVIEN	ABILITY TEAM		V	<u> </u>	9	N	4	3	·		M	/	ےا	0	2	۷ ر	
	В	PRODUC	CY REVIEW		Î	6		·				7 7			district.				
	С	PRODUC	CT MANAGER TEAM SAFETY REVIEW									_							<u></u> _
	D	PRODUC	T MANAGER TEAM EN- ENTAL SAFETY REYIEW		L					-								·.	
	E	PROOUC	T MANAGER TEAM	L	6	0	/	P	1)0	ua	la	2	KA	/	2	/	4	7	6
	F	PRODUC	T MANAGER							ر							2.3	i, ee	
	G	INTERA	GENCY REFERRAL							·					_ 				1 11.
1	Н	соэт-в	ZNEFIT REVIEW			H											1. 1/2	dayi	
	i	PUBLIC	COMMENTS REVIEW									ukiji P				14.			
	J	EEE BR Effica	ANCH INSECTICIDE CY	3.7								÷							
	к	EEE BR	ANCH HERBICIDE CV					왕 왕 5											di.
	L	EFFICA	ANCH FUNGICIOE CY							·			1.4		<u></u>		:		
	М	EEE BR	ANCH ROGENTICIOE										7 3 4 4	1	::: 				
	N	EEF BR	ANCH DISINFECTANT CY										:			4.4.	4		
	0		RY BRANCH CHEMISTRY	*													7		
	Р		ANCH ENVIRON - CHEMISTRY	ل_															
	Q	TOXICO HUMAN	LOGY BRANCH SAFETY																
	R	配巨数 BR M型HTAL	ANCH ENYIROH. SAPETY																
	s															497			
	T			1							- 				.				1.88
PR	oouc	T MANA	SER SIGNATURE				TYPE	OF RE	SPONS									COOL	- 488)

				1.			REGIST	RATIO	N NU	MBER		·····	CYC	LE	2.	0/	TE	RECE	(VE	0
L			REVIEW RECORD G	3	15	9	0	<u> </u>				2				ຳວົ	/	jr.	ブ	1
3,	3C1D	PUBLIC.	ATION NECESSARY	4.	PET	ITIO	NO.								5.	REC	EIVE	O PM	TE#	A M
		YES	Д 100												زم	15	D	۱	Y	(R
6.	MET	HOO OF 9	SUPPORT	7.	PRO	ous	T MAN	AGEA					No).	8 . P	'WOJ	ECT	EOR	£TUI	RN
		24 [] 2 B		y.	B	Ens	5					3	3	Ž,	10)	D .	A Y (Ý	(1)
9, 0	DATÉ	PULLEO	10 DATE PUBLISHED	31.	AC	TION	TYPE					1	COL	DΕ	12.	OUT!	·····	IG O		
		,		1	<u> </u>	2.54	(L)	27/5	510	λΞ	da	19	5	2	JĹ	Ñ () 1°	ĬĬ7		YR
REV SEO.	REVIEW TYPE CODE		REVIEW TYPE	FR.	VIE COO		SI	GNATI	JAE O	FREV	/IEWE	A	CO				EVIE	w co	VPLE.	TEO
25	A C C	ļ			Inicia	115)						w 	COL	ÞΕ	. м		P	AY	,	YR
X	A	REYIEN	YABILITY TEAM	4	14	12	2	MH	can	\L	$\stackrel{/}{\Rightarrow}$		M		0	<u>u</u>	2	6	2	16
1	В		CT MANAGER YEAM	<u> </u>		1			<u> </u>	0						<u> </u>		Ì		
	С		CT MANAGER TEAM BAFEYY REVIEW				.									ĺ		1	į	
	D	PRODUC	C T MANAGEN TEAM EN- IENTAL SAFETY REYIEW													 				
	Ε		CT MANAGER TEAM HISSION REVIEW	1	16	10	E		Dr.	-a/	/ as			2	1	5	یر	1.5	2	6,
	F	₽R DDU¢	CT MANAGER		 	<u> </u>	7		·]
	G	INTERA	GENCY REFERRAL		1	·		· · · · · · · · · · · · · · · · · · ·	'											 [
	н	CO\$T-B	ENESIT MENIEM				·		•	······································										
	ı	PUBLIC	COMMENTS REVIEW									·								<u> </u>
	J	EFFICA	ANCH INSECTICIDE CY																	L
	ĸ	EEF BR	ANCH HERBICIOS GY		<u> </u>															
	L	EEE BR	ANCH FUNGICIOE CY		<u> </u>					·									-	
	М	EEE OR EFFICA	ANCH RODENTICIDE																	
	N	EEE BR EFFICA	ANCH DISINFECTANT CY																	<u> </u>
	0		TRY BRANCH E CHEMISTRY						-											
	P	KEE BR MENTAL	ANCH ENVIRON - CHEMISTRY					······												
	α		LOGY BRANCH SAFETY							······]	<u> </u>
	R	EEE BR. Mental	ANCH ENVIRON- - SAFETY				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~						,							
	s																			
	Т			i																
PRO	POUC	T MANAC	ER SIGNATURE				TYPE (FBEG	PONS	E ,,								-	OOE	
Y	f.		1//	/	2		/	00	4	U							Ì	1	一人	7
L	Sere	سبعيه	- 04 120 L	12	_			1		- C			····						4	<u> </u>

EEE BRANCH REVIEW

DATE:

FISH & WILDLIFE	ENVIRONMENTAL CHEMISTRY	EFFICACY
•		
	·	
•	•	
FILE OR REG. NO.	*	
PETITION OR FXP. PERMIT N	O. FAP #5H5079	
DATE DIV. RECEIVED	6-23-76	
DATE OF SUBMISSION	6-17-76	
DATE SUMMISSION ACCEPTED		
TYPE PRODUCT(S): I, (D) H	, F, N, R, S Bacteriostatic W	ater Filter Media
PRODUCT MGR. NO.	33	
PRODUCT NAME (S)	Hygene Bacteriostatic Water Fi	lter Media
COMPANY NAME	Ionicș, Inc.	
	Resubmission with data	·
CHEMICAL & FORWALATION	Metallic silver 1.05%	
	3	

200.0 Introduction

200.1 Use: Bacteriostatic Water Filter Media .

201,0 Data Summary Background Information

The bacteriological data originally submitted with this petition were also submitted with the application for registration of this product. These data were not acceptable to support efficacy of this product as a water purifier (to render raw water microbiologically potable) as indicated in our letter of July 25, 1975.

The data included in the submission of June 17, 1976 for this petition have been accepted to substantiate bacteriostatic activity for the water filter media itself.

202.0 Recommendations

202.2 Claims not supported by data submitted:

The bacteriolgical efficacy data submitted originally in conjunction with both this petition and the application for registration were unacceptable as indicated in our letter of July 25, 1975.

The data submitted with your letter of June 17, 1976 will not support the claim that less than 50 ppb silver in the water is at an efficacious level to render raw water microbiologically potable. These data were accepted to substantiate bacteriostatic activity for the water filter media itself which is used in housing devices to further process municipally treated tap water by removing undesirable tastes and odors. The silver is an incidental food additive in the tap water so processed.

Since the review of a food additive petition for silver is based on data requirements for residues from a disinfectant to render raw water potable rather than an incidental food additive in tap water caused by leaching of the bacteriostatic used to prolong the life of the filter medta, a new petition should be filed to reflect the intended use pattern.

Additional data required: Because the performance of the water filter media will vary according to the quality of the tap water, the silver tolerance of 50 ppb should be based on data developed with quality parameters which would cause the maximum leaching of silver into the effluent tap water that could be encountered under use conditions. Note the quality parameters defined in the "Interim Requirements for Registration of Bacteriostatic Water Treatment Units for Home Use" (Federal Register, Vol. 41, No. 152, p. 32778-32782, Thursday, August 5, 1976), are:

pH: 6-8
Hardness as CaCO3: 25 mg/l (ppm)
Alkalinity as CaCO3: 20 mg/l (ppm)
Total Dissolved Solids: 10-40 mg/l (ppm)
Temperature: 20°-25°C

The chemical analysis for the tap water used to develop the data submitted indicated that these water quality parameters were not fully met.

203.0 Labeling

The following revisions are required to reflect this product as a bacteriostatic water filter as claimed:

- 1. Revise the claim "Oo not use in combination with other silver disinfecting devices, e.g., silver filters" to read "Do not use other silver-impregnated filter media in combination with Hygene Bacteriostatic Water Filter Media to fabricate or manufacture water treatment products".
- Revise the claim "raw water limitations" to read "tap water limitations".
- Delete "and at an efficacious level".
- 4. Indicate that fabricators or manufacturer of water treatment products are responsible for providing data to support their registration.
- 5. Clarify the function of the silver in the water filter media somewhat as follows: "Silver is incorporated into this water filter media to inhibit the growth of bacteria entrapped in the media when municipal treated water is filtered."
- 6. Identify the claim "Flow rate is not to exceed..." as "Directions for Use".
- 7. On the product label, clarify the claim "Inhibits the growth of bacteria" to read "Inhibits the growth of bacteria in the filter media".
- 8. On the product label, indicate that the product is to be used only for fabricating or manufacturing water treatment products.

Worstay in Torcher

Dorothy M. Portner

8/27/76

Efficacy Section

Efficacy and Ecological Effects Branch



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

1. SAMPLE NO.
1. SAMPLE NO. 112876

2. DATE COLLECTED 3-23-76

The PACIFIC	REPORT OF	ANALYSIS		3.	REGION III
		SAMPLE IDENTIFIC	ATION		
4. LOT OR CODE NOIS	03226B		REGISTRATION NO. 35900-2	6.	ESTABLISHMENT NO. 35900-Pk-01
7. PRODUCT NAME	"HYGENE Bacterio	static Water Filt	er Media ^B		
IONICS, INC. Routes 519 am	NO ADORESS (Include ZII vd 50 Penns. 15017	P code) 9. DE/	ALER NAME AND AOD	RESS	(Include ZIP code)
IONICS, INC. Routes 519 am	d 50	P code) 9. DE/	ALER NAME AND ADD	RESS	(Include ZIP code)

Silver (Metallic) Activated Carbon 98.95%

	TEST		T SD
12. TYPE OF TEST	13. TEST ORGANISM(S)	14. METHOO NO.	4.201
Ager Cup	E. coli Staph. aureus	15. OURATION	24 hrs
		16. CONCENTRATION	
	Pseudomonas fluorescens	17. DILUENT	

Sample was found to possess bacteriostatic activity against Escherichia coli, Staph aureus and Pseudomonas fluorescens.

19. RESULTS Zones of inhibition against: Escherichia coli Staphylococcus sureus 1 1000 Pseudomonas fluorsecens

23. DATE 20. TESTER'S INITS. 21. SIGNATURE OF LAB SUPERVISOR 22. LABORATORY (t

EPA Form 3540-5 (Rev. 7-75)

REPLACES ÉPA FORMS 8500-4 ANO 8500-4A. PREVIOUS EDITIONS OF EPA FORM 3540-5 ARE OBSOLETE.

REGISTRATION DIV. COPY

SAMPLE SUMMARY	DATE RECEIVED	REGISTRATION NO.	112876
ANALYTICAL REPORT	PRODUCT	33300-2	112070
WALL HOVE RELACT			
	Hygene Ba	cteriostatic Wat	er Filter Media
SEALEO	<u></u>		
Seal broken by Dallas Wright	, Jr.		
IDENTIFIEO	11		
"SN 112876 03-23-76 ALDP	Sub 1" CONDITION OF SEALS		LABELING SUBMITTED
	Broken		
Dallas Wright, Jr. by hand DESCRIPTION OF SAMPLE	Broken		<u> </u>
Plastic bag containing broke Code "Lot No. 03226 B"	n seal and one	7 oz. plastic bo	ttle with label.
APPEARANCE			
Black granular solid; no odo			
ANALYSIS	AMOUNT CLAIMED	SATISFACTORY	UNSATISFACTORY
			<u></u>
			
		Ì	į.
•			
	<u> </u>		<u></u>
Method: Silver extracted from 3 hours and standing solution added to as with silver nitrate lated as metallic stated as metallic stated as metallic stated as a second silver average - 1.90% silver average -	g over weekend. n aliquot of sa potentiometric ilver.	Excess sodium mple extract; exally. Silver in	chloride cess titrated
SIGNATURE OF ANALYST	EAA		OATE REPORTED
Jack B. Looker	400		4/27/76
RESERVE SAMPLE AB Tec SEALED			
1ess 30-35 grams "11287	2 . 2	ack B. Looker"	
SIGNATURE OF SUPERVISOR	Mall		DATE 4-27-76

REDISTRATION DIVISION

IDNICS, INCORPORATED Attn: Walter Polens P.O. BOX 99-Bridgeville, PA 15017 NAK & & Wife

Gentlemen:

Subject :

HY GENE

EPA Reg. No. 35900-2

Your letters of February 18, 19, 1976 and

March 4, 1976

The general chemistry data is acceptable with the exception of A.5 and B.4. You should submit details of the atomic absorption and the Volharo Memhods of Analysis.

In regards to your suggested procedure for evaluation of Hydene Model HY-2 cartridge type filter for FPA Registration. Data derived in accordance with the test protocol submitted would meet the bacteriostatic efficacy data requirements indicated in our letter of December 24, 1975 for a unit which processed municipally treated tap water at a flow rate of 3 gpm for a 18,750-gallon volume capacity. The acceptance of the unit for the efficacy claimed is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently prepared document "Interim Requirements For Registering Bacteriostatic Water Treatment Units for Home Use" is enclosed to inform you of the test protocol to be used in testing future water treatment units that you develop. At this interim interval, you have the option of developing data by either the test protocol that you submitted or by the one indicated in the document enclosed.

Your submission of Dewember 5, 1975, in reference to Pool Gene, File Symbol 35900-R, is still under review. Due to the nature of the points raised and/or objections stated in your letter in reference to our previous evaluation of your application, it was deemed necessary that each of the five scientific discipliness concerned remoder their scientific

judgement. Three such evaluations have been made. However, two more are still required. As soon as we have received a response from all of the disciplines involved, the information will be transmitted to you. We expect this review to be completed in approximately two weeks.

Sincerely,

James H. Banks Product Manager 33 Disinfectants Branch (WH-567)

Enclosure

WH-567:DIS:RGD:md:59040:Rm 321 4/23/76



February 18, 1976

Mr. James H. Banks, Product Manager 33 United States Environmental Protection Agency Disinfectants Branch (WH-567) Registration Division 401 M Street S. W. Washington, D. C. 20640

Ref: Your Letter of December 24, 1975 in answer to my Letter of December 3, 1975

Dear Mr. Banks:

I have enclosed with this letter a suggested Procedure for Evaluation Of HYgene Model HY-2 Cartridge Type Filter for EPA Registration. メンター・アンクー・マーマーフ

The reason I am sending this testing procedure along to you before we spend the money to complete this testing is that the last time we had our Hygene material tested, we obtained results that Mr. Brown said would get us a self-sanitizing rating and then after we sent the EPA the results, we were not given a self-sanitizing rating but a bacteriostatic rating.

Our company is a relatively small company and we can not afford to waste money. We ask that you please review this as soon as possible and let me know if we complete this testing, would it suffice to get us a bacteriostatic rating.

I am aware that the labeling would have to be in line with the label we have on our bacteriostatic Hygene material.

We ask that you have this reviewed and contact us as soon as possible.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure

cc: J. D. Collins



March 4, 1976

Mr. James H. Banks, Product Manager (33) United States Environmental Protection Agency Disinfectants Branch (WH-567) Registration Division 401 M Street S.W. Washington, D. C. 20640

Dear Mr. Banks:

Please refer to my letter of December 5, 1975 in reference to Pool Gene File Symbol 35900-R.

I have not had a reply to this inquiry.

I also call your attention to my letter of February 1B, 1976 directed to your attention in reference to a proposed evaluation of our HYgene Model HY-2 cartridge type filter. I have had no answer to this letter either.

Your replies to both of these will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle



February 26, 1976

Correg 35 900

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch, Room 321
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Dear Mr. Banks:

Enclosed you will find a copy of the Application for Supplemental Registration of Distributor that was sent to our company. This was marked "Disapproved" because it did not have the signature of an officer from Ionics, Incorporated.

I have signed this form and returned it. I don't know if this is satisfactory or if you need a complete new application.

If a new application is needed, will you please send one along and we will have it executed.

Your prompt attention to the above will be very much appreciated.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure

cc: Clean Water for America

NOTE: An official of the CLEAN WAXER : FOR AMERICA MUST SUBMIT A LETTER REQUESTING A DISTRIBUTOR OO. NUMBER. ENCLOSE THIS LETTER WITH YOUR COMPLETED EPA FORM 8570-5.

H-TONG MAR 1 5 1976

REPORT OF TELEPHO	NE CALL OR VISITO	R	NOTE: Complete this form. Write "NA" where not applicable.
INCOMING CALL	VISITOR		MAR 1 5 1976
OUTGOING CALL .	CONGRESSIONAL		TIME OF CALL
NAME AND ADDRESS OF CALLER OR VISIT	ron	. "	PHONE NO. (Include Area Code or IDS No.).
FOROX 99 Bridg	Ruille PA	15.017	REGISTRATION, ID NO. DR FILESYMBOL 35 100-2 PM-33
	•		DATE OF LATEST SUBMISSION
BRIEF SUMMARY OF CONVERSATION		-0-	- 0.11 1 -
By kubleen with	your 83	570-5	and letters of
2-26-76			
		*, *, *, *, *, *, *, *, *, *, *, *, *, *	
		:	
ACTION TAKEN OF RECOMMENDED	21. B. XL	2	100 F
(Need your to	A Key. NO	ם ואם בם ח	2 - 0
@ Need your sy	grature !	as off	icial/registront
10 will cond	in the same	time.	and from
8520-5-40	be come	(Del)	and form to
000	90	्र क्षा ()	
1 Ky Jeb		•	
		• .	
		•	
	•		
	a a ree	•	
	<i>:</i> .	• .	
	•		
RECORDED BA (Name)	-	REFERRED TO (A	/ame)
1 - 1 + m		5	•

	Form Approved OMS No. 138 R007
U.S. ENVIRONMENTAL PROTECTION AGENCY	REGISTRATION DISTRIBUTOR
OFFICE OF PESTICIDE PROGRAMS (WH-567) WASHINGTON, D.C. 20480	
APPLICATION FOR SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR	POR EPA USE ONLY (Data Systems 1 - Marion)
(Please read Instructions on back before completing)	н 💮
NAME AND ADDRESS OF BASIC REGISTRANT (Include Zip Code)	PILE SEQUENCE CODE
	PRODUCT NUMBER
I Ionics Incorporated	
P.O. BOX 99	DATE ACCEPTED
· ·	YEAR WONTH BAY
Bridgeville, PA. 15017	DISTRIBUTOR PRODUCT MAME
CHECK IF THIS IS A NEW ADDRESS	
NAME OF REGISTERED PRODUCT	EVALUATION CHECKLIST
HYGENE .	Evaluation characters
PROPOSED DISTRIBUTOR PRODUCT NAME	REGISTRATION NUMBER
r ·	CONFIRMED
NauTilis.	DISTRIBUTOR NUMBER CONFIRMED
NAME AND ADDRESS OF PROPOSED DISTRIBUTOR (Include Zip Code)	
*	REGISTRANT ADDRESS
CHEAN WATER FOR AMERICA	CONFIRMED
	THANC PRODUCT HAME
mismi Beach, FLM. 33140	CONFIRMEO
T L	PROPOSEO DISTRIBUTOR
	PRODUCT NAME ACCEPTANCE
[] CHECK IF THIS IS A NEW AUDRESS	
It is requested that we be permitted to market under the Distributor Product Name	· · · · · · · · · · · · · · · · · ·
and Number specified above.	473
20 10 10 10 10 10 10 10 10 10 10 10 10 10	OIVISION ON THE DATE STANPED
Madeine Bleit Dect trosser 10403/13	
REGISTRANT It is requested that the Registration Record of the basic product specified above 1	
amended to include the Distributor Product specified above.	
SIGNATURE AND TITLE OF REGISTRANT SEE ENCLOSED DATE OCT. 17-71	·
TONECY, inc see enclosed oct. 17-71	
U.S. EPA	
APPROVED - Subject to the conditions specified on the reverse. DISAPPROVED - See reverse for explanation.	
SIGNATURE OF EPA OFFICIAL DATE	
	1.03
EPA Form 8570-5 (Rev. 12-74) PREVIOUS ECITIONS ARE OBSULE	TE- 1 CON 1 CON 1

*Manufacturing process information may be entitled to confidential treatment*_



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Subject: KYgene

EPA Reg. No. 35900-2

Your Letter of Jan. 2D,1976

Dear Mr. Banks:

This is in reply to your letter dated January 20, 1976 in reference to general chemistry data for HYgene.

A.1 You are correct in stating that the active ingredient is essentially 10D% metallic silver with only traces of impurities.

6 V.

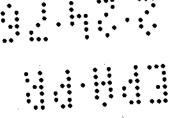
A.2 Correct. Manufacturing process is the same as in Petition 5H5079.

oΚ

A.3 Purity of ingredients used in the manufacturing process of HYgene are as follows:







- Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency

February 19, 1976 Page 2

- A.4 The active ingredient (silver) has been described only by the word "metallic". These other adjectives would also be applicable.
- A.5 I do not understand if you are saying you are going to & send us the information on the testing or if you are B.4 waiting for us to supply you this information.

I trust this is the information you desire.

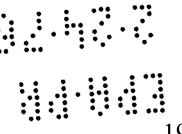
Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

cc: J. D. Collins - Ionics



						1. REGISTRATION NUMBER								С	YCL	€ 2	2. OATE RECE				IVED	
	SUBMISSION REVIEW RECORD G				5	9	0	O	-				72	2			D	٥ ك.		AY 4	*	(R C
3.	3CID	PUBLICA	ATION NECESSARY	4.	PET	TIOI	N NO	•		<u>_</u>	. 					5					ATEA	M
	☐ YES ☐ NO															6	<u>س</u>		DAY YR			
6.	6. METHOO OF SUPPORT			7.		_		NAGI		······································					NO,	8					IETU	RN
		2A [] 28 2C				~~~~~~~~~~	A			بالمراس	22	·····	تـل	3 _	3	M	0	B	Î		/R
9,0	DATE	PULLEO	10 OATE PUBLISHEO	71.			~~~~~~~~~~							, Pt	COO	E 1	2. 0	• • • • • • • • • • • • • • • • • • • •		NG D		/R
<u></u>					~ (tu		-	2973						\$		2_			Ĺ,			<u> </u>
REV SEQ.	REVIEW TYPE CODE		REVIEW TYPE		VIEV COO	E		SIGN	IATU	RE O	FRE	VIEW	ER.	١٨	COM MENT CODE	-	DA [*]			w ∞ AY	WPLE	TED YR
- C	Á		VABILITY TEAM	9	2	<u></u>	(JA	H	ra		4	·		20	1	_ 21	3	7	E .	2	
	В		CT MANAGER TEAM CY REVIEW		L	<u> </u>				_८	2		ノ _							L		L
	С		CT MANAGER TEAM SAFETY REVIEW		 [T	١					
	D	PRODUC	ET MANAGER TEAM EN- ENTAL SAPETY REVIEW		1	1				 -				\top			 					
	E	PRODUC	CT MANAGER TEAM MISSION REVIEW	D	m	>		0	بمير	200	B	p*			722		0	4	,	3	<u>,</u>	4
	F	PR 0000	CT MANAGER		 [-				T		T	<u>_</u>					
	G	INTERA	GENCY REFERRAL							······································			• •			<u> </u>	 			 		<u> </u>
	Н	COST-BI	ENEFIT REVIEW			<u>.</u>											4 					
	1.	PUBLIC	COMMENTS REVIEW			<u> </u>																
	J	EEE BR	ANCH INSECTICIDE																	18 (A) 18 (A)		
	к	EEE BR	ANCH HERBICIDE CY																٥.	ė.		8/g 2-7
	L	EKE BR. EFFICA	ANCH FUNGICIOE CY			 L_						MANAGE		4								
	М	EEE BR EFFICA	ANCH RODENTICIOE												ý á						<i>1</i> 2	
4	N	EEE BR	ANCH DISINFECTANT CY	D	m	P	人	Dr	n 1	0	In	ر ميه				$\int_{\mathcal{C}}$		3	3		7	6
	0	K R SI DUE	TRY BRANCH E CHEMISTRY	ا	277										ijai.				*			
	Р		ANCH ENYIRON - . CHEMISTRY		 												Ī					
	Ω	TOXICO HUMAN	LOGY BRANCH Bafety									.·			manana		_	2/				
	R	EER SR MENTAL	AHÇH ENVIROH- . SAPETY												V. S	.; :a.;						-
	s											·						*				
	T			*.1					WA (1)										.			
PRC	ວບດ	TMANAC	BER SIGNATURE				TYP	E OF	RESP	ONS	E	,		ś						(COOL	
										<u></u>										·		

EEE BRANCH REVIEW

	DATE:	IN	_our	IN	OUT	IN 3/31	OUT 3/31/76
	•	FISH &	WILDLIFE	ENVIRONM	EVIAL CHEMISTRY	EFF:	ECACY
			٠.				
	<			•	,		
		6			25000 0		
•	FILE OR	REG. NO.			35900-2		
	PETITION	OR EXP.	PERMIT NO).			
	DATE DIV	. RECEIV	F.D_		2-24-76		,
	DATE OF	SUEMISSI	ON		2-18-76	:	
			ACCEPTED_			•	
	TYPE PRO	DUCT (S) :	т, 6,) н,	F, N, R, S_	Bacteriostatic	Water Filte	r
	PRODUCT	MGR. NO.	·		33		
					HY-2 Cartridge	Type Filter	
	COMPANY	NAME		Ionics, Inc.			
	SUBMISSI	ON PURPOS	SE	Resubmission	without data		, , , , , , , , , , , , , , , , , , , ,
	CHEMICAL	& FORMUI	ATION				

- 200.0 Introduction
- Use: Bacteriostatic Water Filter 200.1
- Background information: This submission includes a test protocol 200.2 in response to efficacy data requirements indicated in our letter of December 24, 1975.
- 202.0 Recommendations
- 202.1 Claims supported by data derived by proposed test protocol: Data derived in accordance with the test protocol submitted would meet the bacteriostatic efficacy data requirements indicated in our letter of December 24, 1975 for a unit which processed municipally treated tap water at a flow rate of 3 gpm for a 18,750-gallon volume capacity. The acceptance of the unit for the efficacy claimed is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently prepared document "Interim Requirements For Registering Bacteriostatic Water Treatment Units for Home Use" is enclosed to inform you of the test protocol to be used in testing future water treatment units that you develop. At this interim interval, you have the option of developing data by either the test protocol that you submitted or by the one indicated in the document enclosed.

Donothy M Portner Dorothy M. Portner

Efficacy Section

Efficacy and Ecological Effects Branch

	······································	A BE WANTED
- TRYIFM COMMENTS SHEET	1.Application Date	2. Registration H
3.Rempense Code	AND AND AND AND ADDRESS OF THE PROPERTY OF THE	The state of the s
	1. Date Received	5. Telephone Ho.
***		59042
6.Applicant Name & Address		7.Originator
	*	James H. Banks
	* * **	Pm-33
	· · · · · · · · · · · · · · · · · · ·	e de la companya del companya de la companya del companya de la co
		Disinfectants Branch
	· · ·	WI - 567
D. Product Hame		
	L but if at the graph gate	
	MENTS	You
AS-BY We		that you
are soon soing	to submit	letils 7
the AA and	Vothard - met	1.15
the AA sud	Vothard - met	272
the AA. sind	Vothord-meta	3-30-76
the AA sund	Vothard-meta RCJA	3-30-76
the AA sund	Vothard-meta RC Mi	3-30-76
The M. Bud	Vothard-met	3-30-76
The MA sund	Vothard-meta RCJA	3-30-76
The M. sud	Vothard-met	3-30-76
The M. sud	Vothard - met	3-30-76
The M. sud	Vothard - met	3-30-6
The M. Bud	Vothard - met	
The M. Bud	Vothard - meta	3-30-76
The M. Bud	Vothard - meta	3-30-76
The M. Bud	Vothard - met	3-3-6
	Vothard - met	
	Vothard - met	199

			Review under re		
Date of Submissio Product Name Company Long	n: 5-1/-1	Reg/EXP	•	,	ion No
Type of Droduct:	TDUEN	<u></u>	Petition New Pro		
Product Manager (name): B	Type Su	ubmission-New Prod Amended	duct Old Chem Reg. Substant Reg. Nonsubst	ive
Reviews Needed	Rec'd by I	E. Gross Sent	to Reviewer Date	e Completed	Returned to PM
RET				5-26-76	5-26-76
Completeness Revi	ew	Data Review	Waiver Reg	*	
			-	····	
Review Labeling etter gen	. cher	m. Sata	submitted	l. a	41
TEB	4				
EFFICACY	49				
Completeness Revi	ew .	Data Review	Waiver Req	**************************************	
Review Labeling			Marine al		
Letter					
FSN					*
- Completeness Revi	ew	Data Review	Maiver Reg	•	
deview Labeling	· · · · · · · · · · · · · · · · · · ·	<u> </u>		v	
tter	▼			,	
ENV. CHEM.					
Completeness Revi	ew	Data Review_	Waiver Reg	Notice and the second s	
Review Labeling	- In contrast to the state of t			*	
TOX SR.					
Completeness Revi	ew	Data Review	Waiver Reg		
Review Labeling_	•	u			
			*		
LetterCHEM BR.	1	t 1	1 1	1 1	Marting and a second se
Completeness Revi Review Labeling	eA	Data Keview_	Waiver Reg.	**************************************	200

Product ingredient source information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch, Room 321
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Dear Mr. Banks:

Subject: HYgene

EPA Reg. No. 35900-2

Your Letter of Dec. 4, 1975

We have tried to analyze your letter of December 4, 1975 and since you say our letter of November 13, 1975 does not answer the questions you desire. I assume you are asking questions about the finished product of

on their which was

registered with you under Reg. No. 35900-2. I, therefore, assume this is why you were not satisfied with our answers in our letter of November 13, 1975. If this is the case, you would have to get additional information from because we do not know what else they do with the product or add to the product after we ship to them.

If I can be of any further service, please contact me.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

Water

WJP:mle

cc: J. D. Collins



Manufacturing process information may be entitled to confidential treatment

JAN 2

Ionics, Incorporated Attn: Walter Poless P.O. Box 99 Bridgeville, PA 15017

Dear Sir:

Subject: Hygene

EPA Reg. No. 35900-2

We will accept your general chemistry data for HYGEHE media and all products using your media if you verify that the following information is correct:

A.1 Complete composition of technical chemical used as active ingredient:

Edsentially 100% metallic silver formed in situ, with only traces of impurities.

A.2 Manufacturing process of the technical chemical:

Same as in Petition 5H5079

A.3 Purity of starting and intermediate materials used in the manufacturing process:



A.4 Basic physical and chemical characteristics of the active ingredient(§):
Malleable, ductile, metallic, heavy, sensitive to light

Page 2

A.5 Details of the atomic absorption and the Volhard methods of analysis & will be submitted soon.

Your immediate response to this letter is requested.

Sincerely,

James H. Banks
Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)

WH-567::DB:JHBANKS:bab:rm 219WSME, x68815:1/16/76

REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgewille, PA 15017

Gentlemen:

Subject :

HYCENE

EPA Reg. No. 35900-2

Your letter of December 3, 1975

This is in response to your letter of December 3, 1975 in reference to your proposed product named HY2 Water Cleaner.

Although we do expect good engineering principles to be applied to water treatment products utilizing silver filtering media, interpolation and/or extrapolation of data developed to demonstrate efficacy of the filtering media per se is not acceptable to substantiate efficacy of a specific water treatment product.

Silver release data for 10 product units and bacteriological data for 3 product units and 3 corresponding activated carbon controls must be provided to substantiate efficacy of the product identified as "EY2 Water Cleaner" when manufactured with silver.filtering media.

Data developed over the lifetime of the product must be provided to support claims for the removal of pesticides, phenois, and detergents

The earlier information provided that separate EPA Registration Numbers will be required for each individual water treatment product, including replacement filters still applies. The registration number issued (EPA Reg. No. 35900-2) only covers the production and sale of the EYGFNE medium and should not be misconstrued as pertaining to any individually manufactured water treatment unit.

Sincerely,

James H. Banks

Product Manager 33

Disinfectants Branch (WH-567)

WH-567:DIS:RGD:md:59040:12-23-75:Em 321



December 3, 1975

35900-2

Mr. James H. Banks United States Environmental Protection Agency Disinfectants Branch, Room 321 Registration Division (WH 567) OPP-EPA 401 M Street S. W. Washington, D. C. 20640

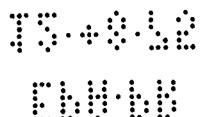
Dear Mr. Banks:

Enclosed with this letter please find a specification sheet on our General Ionics HY2 Water Cleaner.

I wanted to discuss the registration of this cleaner with you during my visit to your office on November 19. Since you were tied up in a meeting that day and I was unable to discuss this in person, I thought I would send it to you in this letter.

Ionics, Inc. is at present producing small HY2 Water Cleaners with plain Activated Carbon. Ionics, Inc. respectfully requests the EPA to grant Ionics, Inc. the usage of its EPA registration number 35900-2 on this HY2 Water Cleaner. We propose to replace the plain Activated Carbon in this filter with our HYgene bacteriostatic water filtering media registered with you under 35900-2. Ionics, Inc. proposes to operate this HY2 Water Cleaner within all of the test flow rates that it supplied to EPA with its request for registration of its HYgene media.

Ionics, Inc. contends that since it performed the tests to show that its product Hygene is an effective bacteriostatic product, if we scale up or down as long as we stay within good engineering principles - EPA should allow the one EPA number to apply to all different sizes of the same product. Ionics, Inc. agrees that if any changes are made to the media or any drastic changes made in design or flow, then this would be a different product and would require a separate registration.



Mr. James H. Banks United States Environmental Protection Agency

December 3, 1975 Page 2

Ionics, Inc. respectfully requests your prompt attention to the above.

Very truly yours,

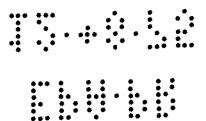
IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

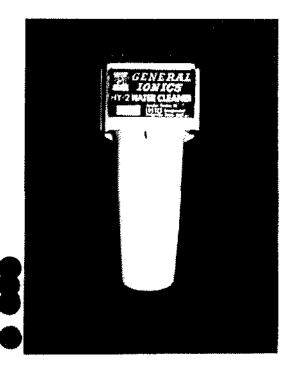
WJP:mle

Enclosure

cc: Mr. Elijah Brown



GENERAL IONICS HY2 WATER CLEANER

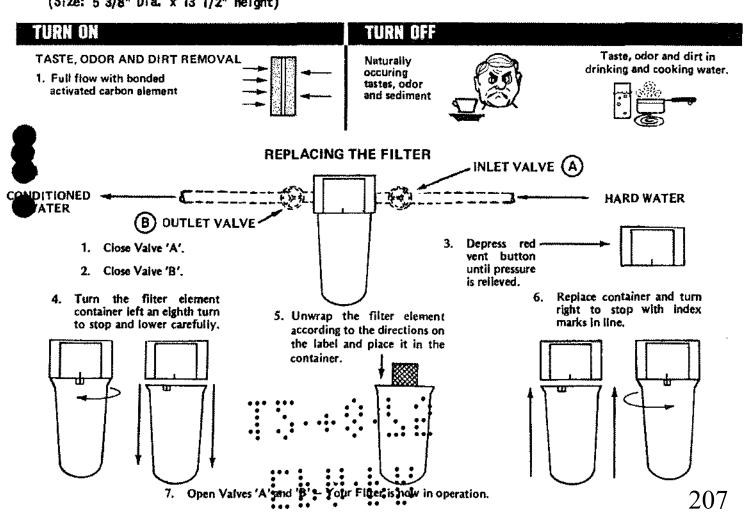


The GENERAL IONICS Hy-2 WATER CLEANER is an Activated Carbon filter, It is designed for efficient removal of organic impurities found in potable water supplies. These impurities include tastes, odors, color, insecticides, pesticides, herbicides, detergents, phenois and other contaminants from both naturel and industrial sources. The Hy-2 Water Cleaner will also remove turbidity and suspended solids found in water to levels comparable with sand filtration.

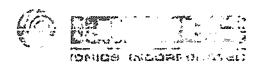
in addition to the absorption and filtration function of the Hy-2 Water Cleanar, it is also capable of concurrently removing excess oxidants such as chlorine used in pretreatment application by municipal water supplies.

Hy-2 WARRANTY: The obligation of GENERAL IONICS, INC., under this warranty shall be limited to the repair or exchange of any part or parts which may thus prove defective under normal use and service within one year from the date of purchase,

(Size: 5 3/8" Dia. x 13 1/2" Height)



Product ingredient source information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 1501 / PHOME A. C. 412 343-1040 TWX 5106973299

December 3, 1975

United States Environmental Protection Agency Disinfectants Branch, Policy 3(1) Registration Division (L. 17) GPP-EPA
401 M Street S. W. Washington, D. C. 2064)

F intion: Mr. James Banks

Dear Mr. Banks:

This letter wil, a thorize you to use information in our file under our EPA Registration No. 35900-2 for the evaluation of a water filter manufactured by

This letter gives you authorization to refer to our file but not to make available to any confidential material in the file.

If you have any questions concerning this, please contact me.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

cc:

Product ingredient source information may be entitled to confidential treatment

REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Gentlemen:

Subject :

HYGENE

EPA Reg. No. 35900-2

Your letter of November 13, 1975

The general chemistry information submitted with the referenced letter in support of support of support acceptable.

- L. Apparently you did not quite understand our request. The general chemistry requirements are in two (2) parts. The first part, (A), refers to the technical chemical used as the active ingredient (in this case-elemental silver) and the second part, (B), refers to the specific pesticide formulation (in this case-- a water filter containing silver and carbon). The information required is as follows:
 - A. Information on the technical chemicals used as the active ingredients in the pesticide, including:
 - Complete composition of the technical chemical, including the chemical names and percentages of impurities;
 - 2. Basic manufacturing process of the technical chemical.
 - Purity of starting and intermediate materials used in the manufacturing process;
 - 4. Basic physical and chemical characteristics of the active ingredient(s), either in technical or purer form;
 - Analytical methods for the principal component(s) and impurities.
 - B. Information on the specific pesticide formulation including:
 - Method(s) of analysis for identifying and quantifying the active ingredient(s) in the pesticide formulation.

- 2. Hote that "basic physical and chemical characteristics", in A(4) above, mean structural formula, melting point, boiling point, vapor pressure, density, hydrolysis rate, solubility, dissociation constants, stability, physical state, color and odor. You have not supplied any of this information.
- 3. Submit more details of the atomic absorption method.
- 4. We accept your storage stability data as satisfactory.
- 5. Your attachment A(Method for determining total silver content of Hygene) is <u>not</u> acceptable because it is incomplete. Exactly how do you analyze for silver? You say "Take aliquot for quantitative analyses of silver." However, that is the end of the method. Please explain.

Sincerely,

7.4

James H. Banks Product Manager 33 Disinfectants Branch (WH-567)

WH-567:DIS:RGD:md:59040:12-2-75:Rm 321

Active to The
Letter dated 11-13-75
Las been placed in the
Confidential envelope.



November 12, 1975

United States Environmental Protection Agency Disinfectants Branch, Room 321 Registration Division (WH-567) OPP-EPA 401 M Street S.W. Washington, D. C. 20640

Attention: Mr. James H. Banks - PM 33

Dear Mr. Banks:

This letter will confirm our meeting in your office on November 19 at 10 a.m.

At this meeting I would like to discuss with you and some of your personnel the application of our Hygene in some of our larger units and also, now that we have an approval on Hygene, I think we could now talk to you about the possibility of using this in our Pool Gene swimming pool unit.

I want to thank you for arranging this meeting and giving us the opportunity of discussing these products with you.

I shall look forward to seeing you at that time.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens

Vice President

NRW-1119-73

WJP:mle

: 1/

i.s. Environmental protection agency office of perticides frograms registration division waimhoton, d.C. 20485 EPA REGISTRATION NUMBER

DATE OF ISSUANCE

NAME OF PESTICIOE PRODUCT

HYDEHE

NOTICE OF REGISTRATION

(Under the Pederal Insecticide, Fungicide, and Rodenficide Act, as amended)

NAME AND ADDRESS OF REGISTRANT

I lonics, incorporated
Attention: Mr. Halter J. Polens
P.O. Box 99
Bridgeville, Fennsylvania 15012

OCT 8 5 105

NOTE: Changes in labeling or formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of the information furnished by the registrant, the above named posticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

I copy of the labeling accepted in connection with this registration is returned herewith.

Registration is in no way to be construed as an endorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pasticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The following paragraphs are applicable only when checked:

- The registration for this product is being issued with the understanding that certain defects in the labeling which are noted below will be corrected as soon as possible. Objection is not raised to the use of the present labeling for a reasonable period of time while fully corrected labeling is being prepared. Three copies of the corrected labeling must be submitted.
- 4. Revice the first two paragraphs of the letter to be sent to well a costoners as follows.

"Mysere was near laboratory tested to decommente dectariostatic activity. The filter madie of a intimit the browsh of bacterie which is entranged Discount the treatment of water."

is. It has been noted that you are not only to distribute an collect and interpretable and a procures or builting, with this are understood that before any such literaturation distributed with this product, it must be first decepted by this govern.

Attachment is applicable.

FIGNATURE OF APPROVING OFFICIAL

DATE

EPA Femilis70-6 14-731 REPLACES OR PORM 9-225 (OCT, 1864) WHICH IS DESOLETE.

Note that this submission was processed and accepted under current requirements. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to PR Notice 75-1.

f. HSrown

Sincerely,

James H. Banks Product Manager 33 Disinfectants Branch Registration Division

Enclosure

Stamped Label

WH-567:DIS:RDOUGLAS:ca:10/29/75:&59041:rm-321

cc: PED



BACTERIOSTATIC WATER FILTER MEDIA HAR THE ACT AND THE PACE AND THE PAC

inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture

EPA Reg. No. 35900-2	EPA Est. No. 35900 PA 01
	LOT NO.
INERT INGREDIENT ACTIVATED CARBON 98.95% DIRECTIONS FOR USE:	NET CONTENTS cu. tt.
	cu, ft. of media. Bed depth must be at least twice the diameter.
	Retain shipping carton and plastic liner for disposing of exhausted filter media with trast
	of General lonics Water Conditioning Equipment
IONICS, INCORPORATED Routes	519 & 50, Bridgeville , Penna 15017

.						1. REGISTRATION NUMBER								CYCLE 2, DA			TE RECEIVEO		
	SUBMISSION REVIEW RECORD G				5	9	00	7 -				2			ŝ	Ö	8	Ž,	کا
	3, 3CID PUBLICATION NECESSARY					4. PETITION NO.										(VE	D PM	TEA	M.
	☐ YES X NO													M		0	<u>^`</u>	· ·	R
	€.	MET	HOO OF SUPPORT	7.	PRO	DHC.	MANA	GER				NO	. 8	3. P	цОJ	ECTE	DR	ETU	RN
	2A 28 2C			,	L	5a	ns	<u> </u>				3	3	м	0	0	A Y	YR 	
	9.0	ATE	PULLEO 10. DATE PUBLISHED	11,	AC	TION	TYPE					COL	DE 1	2. (DUT	301N	G D	4TE	
				K	<u>C</u>	54,	bm/	5510	7 4	villou	Idia	5	/	M	0	6.	ÂY	Y	/R
		≱ Ш		RE	VIE	WER						CON	<i>a</i> . L	DA	TE R	EVIE	v col	MPLE.	TEO
	SEQ.	発表V3E) イヤPE CODE	REVIEW TYPE		nista	£	SIC	NATU	REO	FREVI	EWER	COD	ΙΤ ∮	M	0	0.4	A Y	Υ	YR
		A	REVIEWABILITY TEAM																
		В	PRODUCT MANAGER TEAM EFF(CACY REV)EW				· · · · · · · · · · · · · · · · · · ·												<u></u>
		С	PRODUCT MANAGER TEAM NUMAN SAFETY REVIEW																<u> </u>
		D	PRODUCY MANAGER TEAM EN- VIRONMENTAL SAFETY REVIEW			<u></u>		···-				ļ							
		E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	L	<u>.6</u>		Ľ,) ou	of a	\$	DI	3/		2	2	2	.Z	15
		F	PRODUCT MANAGER	1			· -						_						
		G	INTERAGENCY REFERRAL																<u></u>
		н	COST-BENEFIT REVIEW					·····											
			PUBLIC COMMENTS REVIEW	1		L_	· 						\perp	ſ					L
		J	EEE BRANCH INSECTICIOE EFFICACY			L						┧—	_	***					
		К	EEE BRANCH NERBICIDE EFFICACY]		Ĺ							\perp	1					
	· .	_	EEE BRANCH FUNG GIOE			L						<u> </u>	_{						<u>L_</u>
<u>-</u> ∕∱	./`	М	EEE BRANCH ROOENTICIOE EFFICACY EEE BRANCH DISINFECTANT	_					$\overline{}$			<u> </u>		. [L_
-		N	EFFICACY CHEMISTRY BRANCH		M	1	D	· #	6	(Ch	er	-	-						
		0	RESIQUE CHEMISTRY						~ .				-	ł					
		P	MENTAL CHEMISTRY			Ĺ						-	_		_				
	_	Q	HUMAN SAFETY EEE BRANCH ENVIRON-							<u></u>	·]	
		R	MENTAL SAFEYY															1	
•		S _							<u>.</u>			-	- -		_				
		Ţ										<u> </u>		1					
	PRO))	T MANAGER SIGNATURE	D	,	اد	TYPE O	FRES	PONS	7						ŀ		OOE	_
Y.	PA	Form	es X, Coay 8570-13 (3-75)	سيك				<u>/`</u>		· · ·		<u>-</u>				1			



October 14, 1975

AIRMAIL - SPECIAL DELIVERY - CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESS ONLY

United States Environmental Protection Agency Disinfectants Branch, Room 321 Registration Division (WH-567) OPP - EPA 401 M. Street, S.W. Washington, D.C. 20640

Attention: Mr. James H. Banks - PM 33

Subject: HYGENE

Ionics File Symbol 35900-E

Your letter dated October 9, 1975

Dear Mr. Banks:

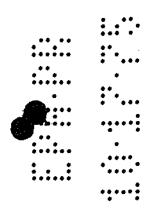
Five finished labels for the above HYgene product are enclosed. On this label, we have made the following changes as requested in your letter dated October 9, 1975:

- 1) We have changed "Self-sanitizing" to read "Bacteriostatic".
- 2) We have changed the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria".
- 3) We have deleted "as a sanitizer".
- 4) We have corrected the typographical error in the spelling of silver.
- 5) In your letter under paragraph 5, you ask us to provide the necessary calculations to verify the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

You may use the following equations to convert the 500 ml/minute and this will show that this is the same as 15 gallons per minute. The equation is as follows:

500 ml flow through column of 250 cc HYgene mineral is directly proportional to 15 gallons per minute per cubic foot of HYgene as follows:

- a) 500 ml/min. = 0.132 gal./min.
- b) 250 cc HYgene = 0.008828 cubic foot
- c) 0.132 gal./min./0.00882B cubic foot = 15 gals. per minute per one cubic foot.



United States Environmental Protection Agency

Attention: Mr. James H. Banks - PM 33

Page 2

6) We have no collateral literature or technical bulletins or brochures that are being distributed with this product at present.

We have enclosed a copy of a letter that is being sent to all of our customers. If any literature or collateral materal is developed to be sent with the product, we will send this to you for your approval.

In your letter dated October 9, 1975 under paragraph "D" 1, 2, 3, and 4 - you asked for additional information required to substantiate the bacteriostatic claim for the filter media.

- 1) Attached please find a letter from Ms. Linda Deans, Manager of Analytical Services for NUS Corporation who did the testing. In this letter Ms. Deans gives the concentration of the artificially contaminated water (inoculum) at the end of the test to ascertain the degree of natural "dieoff".
- 2) The neutralizing solution used contained 5% sodium thioglycollate and 7.3% sodium thiosulfate. One milliliter of this sterile neutralizing solution was added to sterile sample bottles in which 100 milliliters samples were collected for bacteriological testing.
- 3) Attached is a copy of our report "EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION". This was originally sent to you on September 3, 1975. Please note on page one under CHEMICAL, there is a listing of the production lots used for testing. Three of these lots are as follows:

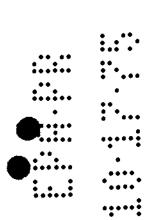
Lot No. 05125, Lot No. 04075, Lot No. 03105

On page three of this report under BACTERIOLOGICAL, we list the three lot numbers used for bacteriological testing.

Lot No. 05125, Lot No. 04075, Lot No. 03105

Please note that these are both from the same lot numbers that we used in the chemical testing.

I refer you to the last paragraph on page two which states "Flow was discontinued to all three columns for a period of eighteen (18) hours." These samples were then acidified and sent to NUS Corporation with the suffix "C" and tested by atomic absorption for silver concentration. This included lot numbers 05125, 04075, and 03105. They were identified then as lot numbers 05125C, 04075C, 03105C. Attached to the above reference report is the NUS Corporation Atomic Absorption Test Report on the silver by lot numbers. None of the three lots went over the 50 ppb after an eighteen hour holding period. This conclusively proves that from these lots even sitting eighteen hours, we did not exceed 50 ppb. These are the lots that we used for the bacteriological tests.



United States Environmental Protection Agency

October 14, 1975

Attention: Mr. James H. Banks - PM 33

Page 3

4) Attached is the letter from Ms. Linda DeansManager of Analytical Service for NUS Corporation that I referred to under "D" - 1. In this letter she mentioned that she used Standard Methods membrane filter technique for the bacteriological assay.

As requested in your letter, in order to expedite the handling of this data, we have returned the duplicate copy of your letter. We respectfully request your immediate evaluation so that we can supply some of our customers who have already been issued there EPA registration number.

Yours very truly,

IONICS, INCORPORATEO Bridgeville Plant

Walter J. Polens Vice President

WJP/mp

cc: Mr. E. F. Brown, Chief

Encls:

*1] •• Five (5) labels

2) Customer Notification of EPA letter

Copy of EPA letter dated October 9, 1975

4) NUS letter from MS, Linda Deans
5) EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION"





Water Conditioning Equipment - Custom Fabrication for the Nuclear, Chemical & Food Industries - Heat Transfer Equipment

NOTE TO EPA: This letter will be sent to our accounts after we have received official notification of having been granted our EPA registration number.

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product Hygene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodent-cide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

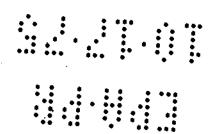
Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure





REGISTRATION DIVISION

IONICS, INC.

Attn: Walter J. Polens

P.O. Box 99

Bridgeville, PA 15017

OCT 09 1875

Gentlemen:

Subject :

HYGENE

F11e Symbol 35900-E

Your submission of September 3, 1975

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

- 1. Change "Self-sanitizing" to read "bacteriostatic".
- 2. Change the claim "Prevent the growth of bacteria" to read "Inhibits >> the growth of bacteria."
- 3. Delete "as a sanitizer."
- 4. Note the correct spelling of silver.
- 5. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.
- 6. Any colleteral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review

Based on an evaluation of the data submitted, the following conclusions were made:

- A. Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- B. Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.

- C. Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours.
- D. Additional information required: To substantiate thebacteriostatic claim for the filter media, the following additional information must be provided:
 - The concentration of the artifically contaminated water (inoculum) at the end of the test is required to ascertak the degree of natural "dieoff".
 - 2) The neutralizer used must be identified.
 - 3) Determinations of the silver content in the effluent from the three test units used to derive the bacteriological data are required.
 - 4) Bacteriological assay method used to derive counts on the effluent from the control and test units must be submitted.

TEPA Reg. No. 35900-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be assued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,

James H. Banks

Product Manager 33

Disinfectants Branch (Mi-567)

Faclosure

A-79 Encl. Duplicate letter

WH-567:DIS:RGD:md:59040:10-9-75:Rm 321



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

October 8, 1975

CERTIFIED MAIL - RETURN RECEIPT REQUESTED DELIVER TO ADDRESSEE ONLY

Mr. E. F. Brown Chief, Disinfectants Branch Registration Division (WH-567) United States Environmental Protection Agency 401 M Street S.W. Washington, D. C. 20460

SUBJECT: HYGENE - Ionics File Symbol 35900-E

Ionics EPA Registration No. 35900-2

Dear Mr. Brown:

This letter will confirm our telephone conversation of Friday, October 3, 1975. From this phone conversation it is my understanding that the United States Environmental Protection Agency will issue to Ionics, Incorporated on their product HYgene EPA Registration No. 35900-2. This number will be issued as soon as you receive the enclosed (5) labels that have the following revisions from the original label sent to Mr. James H. Banks on September 3, 1975.

The revisions on the labels are as follows:

- 1. We have changed the word "Self-sanitizing" to "Bacteriostatic".
- 2. We have changed the claim "Prevents the growth of bacteria" to "Inhibits the growth of bacteria".
- We have deleted "As a sanitizer".
- 4. We are providing the following necessary calculations to verify that the flow rate of 15 gpm/cu.ft. recommended on the label is comparable to the flow rate used in our laboratory experimentation studies. In these studies we used 500 ml./min. flow through a column of 250 cc of Hygene mineral. This is directly proportional to 15 gpm/cu.ft. of Hygene as follows:
 - a. 500 ml./min. = 0.132 gpm
 - b. 250 cc HYgene = 0.008828 cu.ft.

c. 0.132 gal./min./0.008828 cu.ft. = 15 gal./min./cu.ft by direct proportion.

Supplied of the Supplied of th

REGISTRATION DIVISION
PESTICIDES, EPA

Registration Division (WH-567) United States Environmental Protection Agency October 8, 1975 Page 2

It is our understanding that we are to provide you with copies of any collateral literature such as technical bulletins and brochures distributed in connection with this product for your review. At the present we have no literature that will be sent with the product. We are enclosing a copy of a letter we are sending to some of our potential customers.

I would like to take this opportunity to thank you and all of your staff for the cooperation we received.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosures

Mr. E. F. Brown

Chief, Disinfectants Branch

cc: Mr. James H. Banks





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment - Custom Fabrication for the Nuclear, Chemical & Food Industries - Heat Transfer Equipment

This letter is to inform you that Ionics. Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product Hygene.

Hygene has been registered under the Federal Insecticide/Fungicide/Rodentcide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460 REGISTRATION DIVISION

IONICS, INC.

Attn: Walter J. Polens

P.O. Box 99

Bridgeville, PA 15017.

Gentlemen:

Subject :

HYGENE

File Symbol 35900-E

Your submission of September 3, 1975



The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

- 1. Change "Self-sanitizing" to read "bacteriostatic".
- 2. Change the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria."
- 3. Delete "as a sanitizer."
- 4. Note the correct spelling of silver.
- 5. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.
- 6. Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review.

Based on an evaluation of the data submitted, the following conclusions were made:

- A. Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- B. Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.



- C. Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours.
- D. Additional information required: To substantiate thebacteriostatic claim for the filter media, the following additional information must be provided:
 - 1) The concentration of the artifically contaminated water (inoculum) at the end of the test is required to ascertain the degree of natural "dieoff".
 - The neutralizer used must be identified.
 - 3) Determinations of the silver content in the effluent from the three test units used to derive the bacteriological data are required.
 - 4) Bacteriological assay method used to derive counts on the effluent from the control and test units must be submitted.

"EPA Reg. No. 35900-2" is being reserved for this product. This must appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

Sincerely,

Kuth Kanglas for James H. Banks

Product Manager 33

Disinfectants Branch (WH-567)

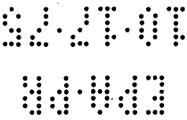
Enclosure

FINISHED LABELING

Finished labeling is defined as the complete markings and text that appear on or accommany the product. Finished laheling must be legible and the granhic design must not be misleading.

Submitting Procedures.

- I. When screen printing or embossing is used to print labeling directly on the container (cans, bottles, hoxes, etc.), do not submit the containers. Such labeling should be submitted after it is reproduced as follows:
 - A. Screen Printing. Request your nrinter to supply finished copies of the labeling on paper for convenient filing. Copies may be obtained by taping a piece of naper on the container as it goes through the printing process.
 - B. Embossing. Photo copy this labeling.
- II. When paste-on labeling is used, submit the actual labeling.
- III. When the labeling involves large containers such as bags or boxes, submit legible, whoto-reduced copies indicating the fraction of the actual size. The actual bags or boxes are not accentable and will be returned. If the whoto-reducing works the labeling illegible, any one of the following methods for submitting finished labeling would be acceptable:
 - A. Photo-reduce the labeling to an acceptable size which would fit in a letter-size file folder.
 - B. Photo-reduce the labeling in sections, so that each sheet is approximately 8-1/2 by 11 inches, or
 - C. Photo-reduce the labeling to 8-1/2 by 11 inches, and submit the labeling text in typewritten form.
- IV. When the labeling is smaller than 40 square inches, conies should be attached to a sheet of namer (8-1/2 by 11 inches).





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment - Custom Fabrication for the Nuclear, Chemical & Foud Industries - Heat Transfer Equipment

NOTE TO EPA: This letter will be sent to our accounts after we have received official notification of having been granted our EPA registration number.

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product HYgene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodent-cide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

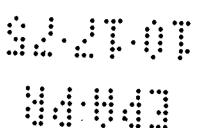
Very truly yours,

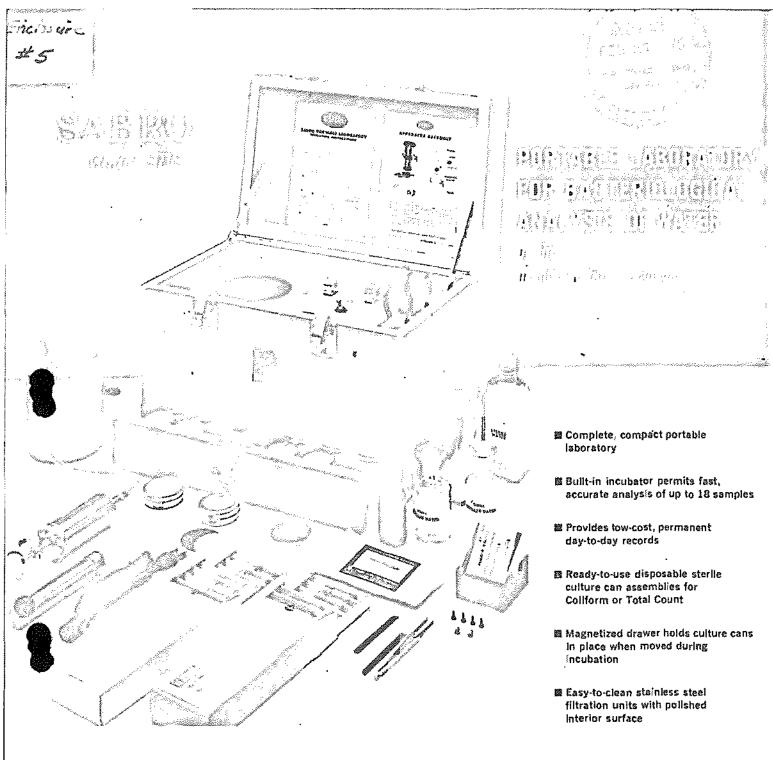
IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure





The portable Sabro Laboratory, using the Membrane Filter Technique, is in daily use throughout the world. It has been given the status of Standard Procedure in the 11th edition of Standard Methods for the Exami-

nation of Water, Sewage and Industrial Wastes, published jointly by the American Public Health Association, the American Water Works Association, and the Federation of Sewage and Industrial Wastes Association.



IONICS, INCORPORATED

P.O. Box 99, Bridgeville, Pennsylvania 15017 (Pittsburgh District) 65 Grove Street, Watertown, Massachusetts 02172 (Boston District)

SABRO PORTABLE LABORATORY

· MEMBRANE FILTER TECHNIQUE

FOR BACTERIOLOGICAL EXAMINATION OF WATER

'I'ln Saliro Portable Laboratory, employing the Membrane Filter technique, provides accurate and rapid bacteriological analysis of water. The incubator, built into the laboratory, permits incubation of water samples in 18-20 hours and temperature contral within +1 F. As many as 18 samples can be incubated simultaneously with samples held firmly in place inside the incubator drawer to permit transparting the lab during incubation.

Disnosable, sterile culture can assemblies are ready for use, minimizing expense and trouble in preparing equipment. Incubated membranes provide safe and permanent records of the examination when treated with a 10% glycerol solution. The Sabro Laboratory rechnique permits permanent day-to-day records at

very low cost.

The Sabro Model SBS-1 contains stainless steel apparatus for the filtration procedure. This appaatus is satin-finished outside and the funnel is marror-polished inside to minimize adherence of aganisms during testing. All necessary equipment air Coliform or Total Count Determinations is contained in the laboratory, including forceps, vacuum pump, bottles for sterile rinse water and reagents. The laboratory operates from any 110 volt, 60 cycle, A(' electrical outlet, although converters are available for operation from automobile batteries. Nickelcadium batteriés also may be used as a power source. In addition, motors and converters for other power

characteristics are available.

An integral part of the Sahro Lahoratory is its incubator. The motor, with a squirrel cage blower, supplies both the heat and air circulation in the incubator, guaranteeing uniform temperature in the incubating chamber. The inculator drawer is magnetized so that the culture cans are held firmly in place and the drawer is held closed by magnets. Incubator temperature, held to within 1 F., can be checked at all times by a dial thermometer.

The disposable culture can assemblies consist of a sterile, labeled culture can containing a sterile membrane filter and a sterile absorbent pad together with a sterile ampoule filled with nutrient (M Endo Broth for coliform determinations. Brain-Heart Infusion Broth for total counts). The ampouled nutrient has a one year shelf life and gives outstanding colony recovery.

Use of these culture can assemblies saves time and money as it does away with the labor and breakage entailed in proparing nutrients, dish washing, tube

plugging and sterilizing.

The outstanding feature of the Membrane Filter technique over the MPN (Most Probable Number) technique is that the entire incubation period is completed in approximately 18-20 hrs. Where the Membrane Filter technique is used, the Sabro Laboratory offers fast, accurate analysis as well as permanent records of each water examination.

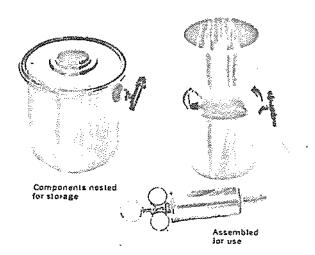
Model SBS-1 FILTRATION APPARATUS

The stainless steel testing apparatus for bacteriological analysis of water by the Membrane Filter technique is heavy-duty, high-quality laboratory equipment. Being stainless steel throughout, it is durable, unbreakable and saly cleaned. All components of the apparatus nest within he flask for storage, so that it occupies very little space.

The assembly consists of a 500 ml mirror-polished funnel, a 500 nil flask, the membrane filter holder, and a doubleacting valve. The filter holder makes up the sealing lid of the flask, and in its center is mounted a porous stainless steet insert. The membrane is laid on this insert, and it is through the membrane and this insert that the water being tested must pass to get from the funnel to the flask.

The entire assembly can be flame-sanitized or sterilized in an autoclave.

The funnel is 500 ml capacity; and is locked simply and firmly to the filter holder in such a manner that it cannot damage the membrane fifter.



A PARTIAL LIST OF SABRO MF EQUIPMENT USERS FOR WATER AND WASTE TESTING

U.S. Public Health Service-U.S. Public Health Service— all Legional engineers U.S. Rational Park Service U.S. Indian Service International Cooperation Agency (Kores, Viet Rahi, Thadaod, Turkey, Frant U.S. Armed Forces World Health Organization City of Pulsburgh City of Pulsburgh City of Pulsburgh

1 11-18

State of Pennsylvania State of Pennsylvania
State of Hilmois
Union Carbide Corporation
University of North Carolina
W. R. Birce & Company
Gull Oil Corporation
Philos Corporation
Radio Corporation
Radio Corporation
Radio Corporation
Radio Corporation
Trans World Authors Hagan Corporation
Ouke Power Conipany
Britist European Airways
American Water Works Service Company
Western Electric Company
Unimalic Engliscering Co.
Duquesne Light Company
General Water Works Management and
Service Company
United Nations Children's Fund (UNICEF)



IONICS, INCORPORATED

P.O. Box 99, Bridgeville, Pennsylvania 15017 (Pittsburgh District) 65 Grove Street, Waterlown, Massachusetts 02172 (Boston Oistrict)

- en de la companya de la companya de la companya de la companya de la companya de la companya de la companya de La companya de la companya de la companya de la companya de la companya de la companya de la companya de la co
- Modern Community of the Com
- If a nator solderer is to an esem it must be included before the dispute unit, anhough it will not alter the prevator of the HYgene System. Otherwise, her silver (the germicide) from the HYgene will be removed by the soldering process.

Post treatment of not required with Hygene as it is with conclusation. The optivisisd carbon base of the Hygene medium also removes before part to a fine at water.

- Q. How can the HYgene system by tested to be certain it is operating properly and killing the harmful bacteria?
- A. There are two methods of testing the HYgene trested water:
 - e by bacteriological analysis to be certain the system is destroying the pathogenic, disease-carrying bacteria. This test can be an with the use of the lonics SABRO bacteriological testing equipment or by a local testing laboratory or hospital.
 - * By silver residual test to determine if the consisting agent is present in sufficient quantity to goe an effective kill of the bestera. The solver constitutions can be determined by the town horize Silver Test in a manufactured by Labroue Chemical Company of Chaptersoum, Maryland This load but is eveniable from longs or LaMotte Chemical Company Company.



WATER
PURIFICATION
PROCESS



P.O. BOX 99 * BRIDGEVILLE, PA. 15017 INTERNATIONAL WATER CONSULTANTS AND EQUIFMENT MANUFACTURERS * MEMBER WATER CONDITIONING FOUNDATION AND THE WATER CONDITIONING ASSOCIATION INTERNATIONAL

Liholo USA H-174

- Q. What is HYgene?
- The physica characteristics of HYgene are comparable to those of granular activated carbon upon which a silver coating has been deposited. Carbon was chosen as the carrier material because of its exceptionally high available surface area for the deposit of silver.
- Q. How does HYgene purify water?
 - Silver, which has been chemically plated onto activated carbon, is the purifying agent. As contaminated water passes through a layer or bed of Hygene material small quantities of silver—less than 50 parts per billion (ppb)—are dissolved. It is this trace amount of silver which destroes the pathogenic organisms found in polluted water.
- Q. Does silver from the HYgene process have a toxic effect on humans?

The grant of the grant that a larger species in some

And the second of the second o

read, y deposited in the body, it is not particularly toxic. The limitation is intended, however, to guard against argyrosis, which is only of cosmetic significance and occurs very rarely and only when soong concentrations of silver are consumed. The HYgene process produces a water effluent with such a low silver content that no toxic effect, cosmetic or otherwise, will occur.

- Q. Has the lonics HYgene process been approved by the federal and state health departments? -
- A. Health departments do not approve methods used for sterilizing water. Health authorities do demand that effluent water from any of the

following methods comply with its set standards, both chemically and bacteriologically. Ionics HYgene process will produce water within these acceptable standards.

The process used for water purification is an individual choice. Chlorination, ozone, iodine, ultraviolet radiation, silver filtration are some of the alternatives.

Q. How is HYgene used?

A STATE OF THE STATE OF

A. There are many application requirements for Hygene ranging from small field or emergency drinking water kits to large industrial/municipal water purification systems. Hygene media is most effective in a compact layer or filter bed system where the raw water passes through a column of material at a given flow rate, or for a mandatory predetermined contact time, in order to destroy bacteria.

A. C. C. C. C. A. Markey Campering of the Society Street

The property of the state of th

Q. Can his pose be used in the home?

discharged miles away, making it practically impossible to trace. When this contaminated water is recognized, the homeowner must make a choice of available means to purify the water. Hygene equipment is sate, reliable and economical for home use.

- Q. Is the HYgene system a more expensive method of purifying water than chlorination?
- A. Surprisingly, HYgene is generally less expensive over a given period of time. The initial cost or capital investment for either method of water purification is approximately the same. The chlorinated system, after installation, re-

quires continuous operational costs for social chemicals and frequent carbon recording to also demands constant maintenance such as frequent equipment adjustments and a rigid schedule of solution preparation. The HYEAR esystem, on the other hand, operates completely free of additional chemicals and with a minimal amount of maintenance required for periodic backwash—every four to six weeks—to maintain a clean filter bad. The backwash requirements of the HYgene filter depend upon the turbidity of the raw water.

- Q. What is the life expectancy of an lonics Hygene filter?
- A. The treating capacity of the Hygene filter is directly related to the amount of medium in the unit. Each cubic foot of Hygene material will sterilize 750,000 gallons of contaminated witer under normal or alreade operation and discrete to the contaminate of

calculating this interpretation of a water meter.

- Q. Is a retention or holding tank necessary following the HYgene filter?
- A. As with chlorination, holding time is recommended following Hygene treatment to prov de residual bacteria kill.
- Q. What are the filtration characteristics of HYgene?
- A. The hydraulic behavior of a Hygene bed is identical to that of a comparable 12 x 30 meters carbon filter.





GENERAL IONICS®

HYgene' WATER PURIFIER

APPLICATIONS:

- Purification of water for homes, hotels, motels, cottages, institutions, industrial plants, commercial plants, commercial buildings, shipboard, air fields, construction camps, etc.
- . Slime suppressant in cooling systems and air conditioning systems.

OPERATION:

The HYgene Process kills water-borne intestinal disease carrying bacteria such as those producing typhoid, paratyphoid, cholera, bacillary dysentery and other such diseases spread by drinking water. The purifying agent employed is a silver salt of complex chemical structure which is deposited on activated carbon. While the silver purifies the water, the activated carbon in the system improves the taste, odor and color. Trace amounts of silver released into the vrater continue to maintain purity long after it passes through a HYgene filter bed. HYgene will purify any water which is "bacteriologically accepted for treatment" as defined by the United States Public Heakth Service Manual, RECOMMENDED WATER-SANITATION PRACTICE. A 10 to 30 minute holding period of the HYgene system effluent is recommended to insure 100% kill.



- · Pure, odorless, sparkling clear water.
- · No additions of chemicals required.
- . Non-irritating to eyes and mucous membranes.
- · Unaffected by exposure to light.
- · Unaffected by exposure to increased temperature.
- · Simple and economical to install and maintain.
- No moving mechanical parts to maintain.
- · Periodic backwash keeps system functioning properly.
- Produces potable water to meet U.S. Public Health standards.

RAW WATER LIMITATIONS:

For reliable operation of the HYgene® system, the following are raw water limitations:

Chlorides: 500 ppm maximum Sulfates: 2000 ppm maximum

Iron: 2 ppm maximum. Most raw waters high in iron content can be pre-treated for its re-

moval before HYgenes treatment.

Color: 20 ppm maximum Turbidity: 5 ppm maximum

pH: 5.0 to 8:5

Temperature: 40 F to 85 F

Hydrogen Sulfide: If present, its removal is recommended.



HYgene' Specifications

Madel	Flow Rate max, gpm	Treating Capacity gailons	Oper. Pressure P\$1	HYgena⊹ Mineral cu. II.	Uni Hgl.	t Oimen. Flr. Sp.	Recommended Size for holding lanks
HY45	4.5	750,000	20-100	1,5	60"	10"x20"	80 to 150 gal.
HY90	9.0	1,500,000	20-100	3,0	65"	14"x25"	150 to 300 gal.

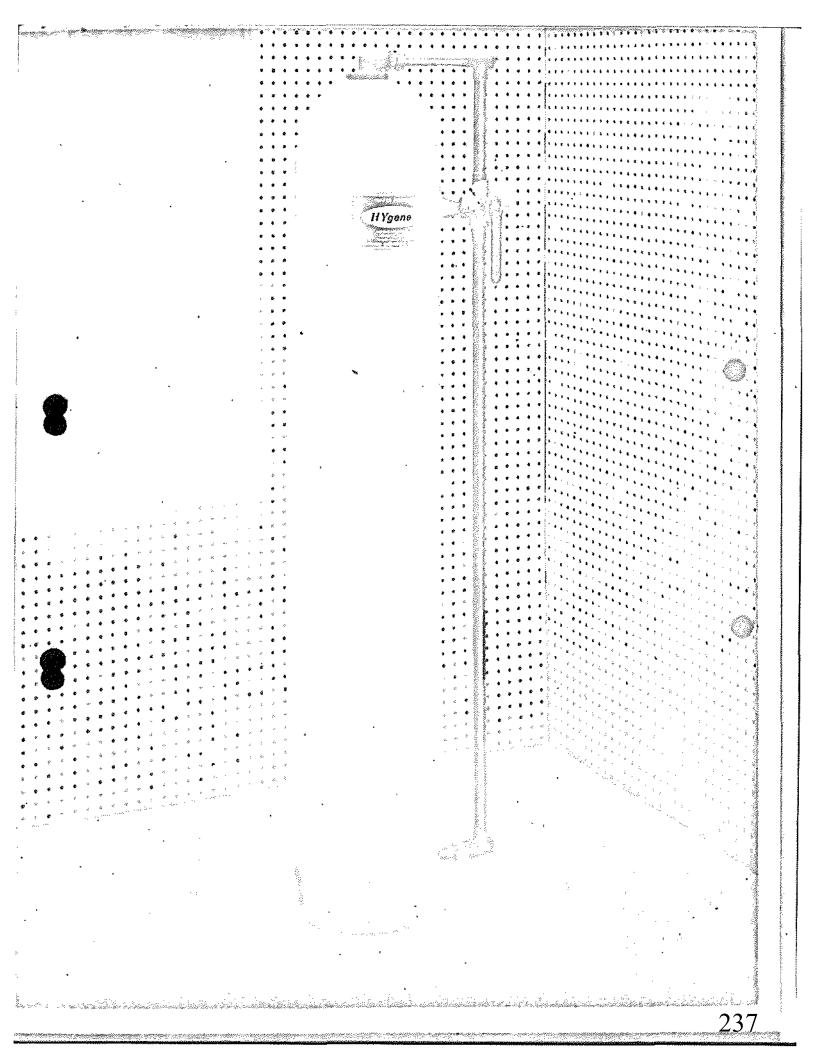
Fiberglass Tank Specifications: Hygene® pressure tanks are made of fiberglass material. These units are available from stock in the two sizes listed above. Purifying units of greater capacity or a special design to meet unusual flow or application requirements can be supplied.

NOTE: When installed and operated according to specifications, water treated by the HYgene Process will meet the bacteriological standard for potable water as established by the U.S. Public Health Service.

Holding Tanks: Storage tanks may be purchased from Jonics, Inc. or from your local supplier.

- IONICS, INCORPORATED

MANUFACTURERS OF GENERAL IONICS*WATER CONDITIONERS
P. O. BOX 99 * BRIDGEVILLE, PENNSYLVANIA 15017 (Pittsburgh District)
INTERNATIONAL WATER CONSULTANTS AND EQUIPMENT MANUFACTURERS
Member Water Conditioning Foundation and Water Conditioning Association International



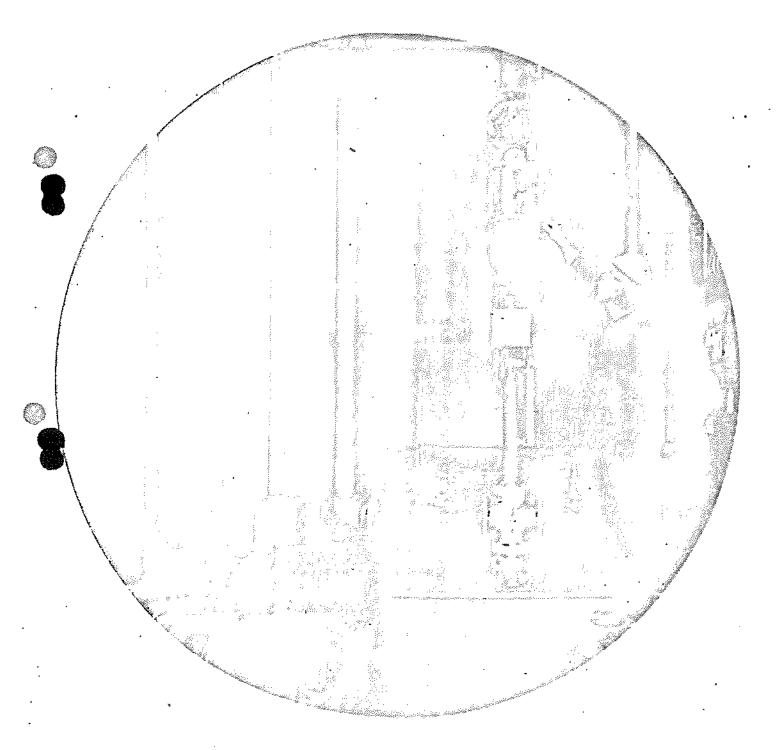


ENCOMMENT OF



WATER PURIFIERS

SILVER/ACTIVATED CARBON FILTRATION SYSTEMS TO PRODUCE SPARKLING BACTERIOLOGICALLY PURE WATER





WATER PURIFIERS

...SET NEW STANDARDS FOR SAFETY

In the silver/activated carbon system the silver purifies the water while the activated carbon removes objectionable taste, odor and color. Additionally, HYgene purified water is unaffected by sunlight or temperature increase, and the silver ions also provide a residual effect to maintain water purity long after passing from the filter bed.

Sabro bacteriological testing

The lonics SABRO Portable Laboratory provides equipment necessary for the bacteriological examination of water. This membrane filter (MF) technique used by SABRO has been given the status of a Salard Procedure in American Public Health Albertalion's Standard Methods. The SABRO MF-mand ollers fast, accurate analysis as well as a perment record of each water examination.

SABRO Portable Laboratories are in continual use by Pennsylvania and other state Departments of Health and Environmental Engineering, U. S. National Park Service, U. S. Indian Service, U. S. Armed Forces, International Cooperation Agency and the World Health Organization.

Raw water limitations for HYgene

Reliable long-term operation of HYgene water purifiers can be expected if the process is kept within the following raw water limitations:

Chlorides.....500 ppm maximum Sulfates.....2000 ppm maximum

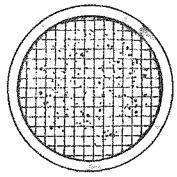
raw waters high in iron content can be pretreated for its removal before HYgene treatment

Color......20 ppm maximum Turbidity......5 ppm maximum

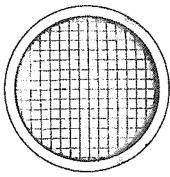
pH5.0 to 8.5 Temperature40°F to 85°F

Hydrogen Sulfide. If present, its removal is

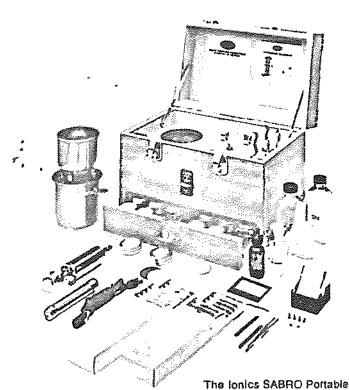
recommended



Before HYgene treatment the coliform culture shows pathogenic disease-carrying bacteria in raw water supply.



After Hygene treatment the clear culture above indicates the bacteria have been destroyed.



Laboratory using the membrane

filter technique is in daily use throughout the world.



ionics, incorporated

P. O. Box 99 • Bridgeville, Pennsylvania 15017 International Water Consultants and Equipment Manufacturers



WATER TREATMENT SYSTEM...POLISHES AS IT PURIFIES

The HYgene water purifier is a silver disinfectant process that will purify any water bacteriologically acceptable for treatment as defined by the United States Department of Health Service Manual. The system is particularly effective as a disinfecting process against pathogenic intestinal organisms found in water, including germs that cause typhoid fever, dysentery, cholera and diarrhea.

In addition to its purifying qualities, HYgene units filter the water and remove objectionable taste, odor and color without the use of chloring or other chemicals.

Filtration/flow rate capacities

Under normal operating conditions HYgene water purifiers will treat an average of 750,000 gallons of raw water per cubic foot of mineral. HYgene units are designed for a flow rate of 3 gallons per minute per cubic foot of purifying agent.

A simple backwashing of the unit is all that is necessary to keep HYgene functioning properly and maintain its purifying, polishing and filtration efficiency.

Operation

The principle of the HYgene process is sliver ions dissited on an inert carrier in an oligodynamic or fixed divided form in such a way that the solubility is litted to meter trace quantities. Contaminated water contacting the purifying agent dissolves very minute quantities of silver. The trace amounts of silver released into the water purifies and continues to maintain purity long after the water passes through the fifter bed.

A storage reservoir following the filtration bed is recommended. A 10- to 30-minute holding period of the HYgene system effluent is sufficient to insure a 100% kill. The effluent is unaffected by exposure to light or increased temperature.

Standard sizes and specials

lonics manufactures standard HYgene fully automatic equipment for maximum daily production rates from 20,000 gallons up to 210,000 gallons. Larger units of special design and capacitles can be engineered and manufactured by ionics. Under average conditions the treating capacity of the purifying agent can run from 4 million gallons in the HY-160 model to 36 million gallons in the HY-1470.

In addition to these commercial/industrial sizes, ionics manufactures two domestic units with capacities of ¾ million and t½ million gallons.

HYgene fully automatic industrial/municipal potable water treatment systems

	Flow Rate	Treating	UVaaaa	Max. Daily		Unit (noienamlC		Recommended Nominal		
del	Maximum [GPM]	Capacity (Gallons Per Charge)	HYgene Mineral (Cu. Ft.)	Production (Gals/24 Hrs. @ Max. Rate)	Hgj.	Floor Space L x W	Tank Dlameter	Valve & Pipe Size	Holding Tank Size (Gallons)		
HY-160	r s	4,000,000	5,5	20,000	64"	24" x 34"	20*	1¼″	500		
HY-240	24	6,000,000	8.0	30,000	66"	28" x 40"	24"	11/4"	750		
HY~360	36	9,000,000	12.0	50,000	68"	34" x 46"	30″	11/2"	1100		
HY~540	54	13,500,000	18.0	75,000	70"	36" x 52"	36°	2°	1600		
HY-720	72	18,000,000	24.0	100,000	72*	42" x 68"	42"	2*	2200		
HY-960	96	24,000,000	32,0	130,000	74"	48" × 74"	48"	21/4*	3000		
HY-1200	120	30,000,000	40.0	170,000	76″	54" x 89"	54"	2У₂″	3600		
HY-1470	1'47	36,000,000	49.0	210,000	78″	60" x 95"	60″	2W*	4500		

Reliability

A major part of the research and development Investlgation on the behavior of disinfection with silver was carried out at the Johns Hopkins University Department of Sanitary Engineering under the direction of Dr. Charles E. Renn. Also, Ionics Quality Controt Department continually checks the physical and chemical characteristics of Hygene mineral to assure that the special properties are maintained.

HYgene completely automatic units mean just that. Water purifiers installed in the United States and elsewhere have produced remarkable records of trouble-free performance involving many sources

of water.

HYgene advantages vs. chlorination

The HYgene system of water purification has a number of advantages over conventional chlorination systems.

Characteristic	HYgene	Chlorination
Medicinal Tasle	None	Yes
Objectionable Odor	None	Yes
Handling of Dangerous Chemicals	No	Yes
Irritation to Eyes and Mucous		
Membranes	None	Yes
Affected by Sunlight	No	Yes
Loss of Residual Effectiveness	No	Yes

In addition to these considerations, over-all cost is a major concern. On a strict comparison of equipment costs the chlorination process appears less expensive. However, when real maintenance and blant operation expenses are considered, the HYgene treatment becomes quite competitive. As an example, the HYgene system

eliminates the purchasing, storage and handling of potentially dangerous chemicals.

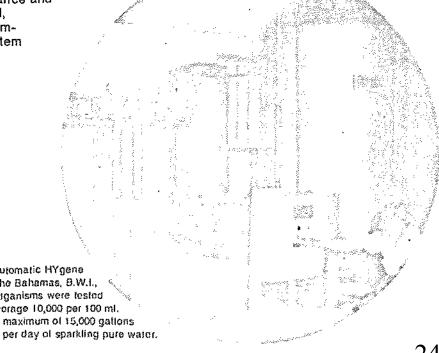
Commercial and industrial chlorination systems demand the attention of an operator to continually monitor chlorine feed as well as switch the spent chlorine tanks. In most cases these assignments involve one extra man on the work force. Hygene units at the same installation eliminate this costly overhead burden. All that is required of the Hygene system is a periodic backwashing to keep the unit dispensing silver at a predictable rate.

Applications

The front cover illustration of this brochure is a Hygene water purification plant built for United Engineers & Constructors at Martins Creek, Pennsylvania, site of a new power plant for Pennsylvania Power & Light Company. This treatment facility turned bacteriologically contaminated well water into potable drinking water in excess of 100,000 gallons per day.

Practically speaking, most any residential home, commercial, Industrial and Institutional plant or small municipality can take advantage of the HYgene water purification process. Here are a few examples:

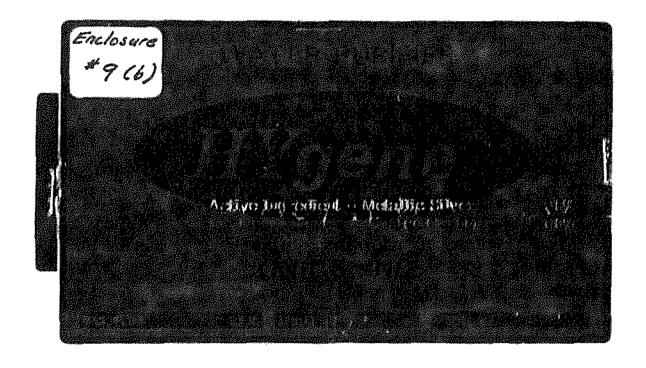
Air Fields Industrial Plants
Commercial Plants Institutions
Construction Camps Motels
Cottages Office Bulldings
Homes Shipboard
Hotels



One of three fully automatic HYgene water purification systems installed in the Bahamas, B.W.I., where pathogenic intestinal organisms were tested and found to average 10,000 per 100 ml.

Each unit produces a maximum of 15,000 gations ner day of spakling pure w

2141 15



Enclosure # 9 (a)



WATER PURIFICATION MEDIA

- · Disinfects without the use of chlorine
- · Produces potable water to meet USPH standards
- · Removes objectionable taste, odor and color

STORAGE OF HY	GENE MATERIAL	.: Store in cl	osed container whi	ch excludes moist	ure and
chemical fumes.	Active Ingred	ient - Mei	allic Silver	1.05%	
	Inert Ingredie	ent - Activ	rated Carbon	98.05%	
Contents:	cu. ft.	•	Lot No	·····	
			Code		

· Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

IONICS, INCORPORATED / Routes 519 & 50, Bridgeville, Pennsylvania 15017

Trademark registered

Deb. BRANCH RENTEM

D'ATTI	INCYI	1.1/ (00)	IN 9/25//5001 9/30/75
	FISH & WHDLITE	EWINONSTRIAL CHESTOTRY	HPFICACY
FHE OR	1973. NO. 3	5900-E	
PETITAO	N OR EKU. PURSIT N	Ö	and the second s
		9/5/75	
DATE OF	SUBMISSION	9/3/75	
DATE SU	PHISSION ACCEPTED		
		, P, N, R, S Self-sanitizin	
FRODUCT	HAR. NO. 33		
		e Self-sanitizing Water Filter	
COAPANY	NAME Ionic	s, Inc.	
SULALISS	TON PURPOSE R	esubmission with data	
CHEMICAL	L & FORWHATION	metallic silver 1.05%	

- 200.0 Introduction
- 200.1 Use: Self-sanitizing Water Filter Media
- 201.0 Data Summary
- Abstract of test reports: Thirteen test columns (2" I.D. and 12" ht.), each containing 250 cc of filter media for a bed depth of about 5" per column, were challenged intermittently to 2000 gallons of dechlorinated tap water at a flow rate of 500 ml per minute. Ten columns were used for chemical determinations of silver release in the effluent. Bacteriological testing was conducted with the other three test columns and three control columns, containing 250 cc of untreated activated carbon which were tested simultaneously with test columns. Each column was challenged with 120 ml (approximate void bed volume) of dechlorinated tap water seeded with Escherichia coli and allowed to remain in contact with the filter bed for 10 hours before the columns were drained and the effluent assayed.
- 201.1.1 Brief description of tests: The chemical determinations for silver were done by the Atomic Absorption Method. The bacteriological samples were placed in an unspecified neutralizing solution and assayed by an undisclosed bacteriological method.
- 201.1.2 Data summaries: The bacteriological data provided for a 10-hour holding period are indicated below:

Sample Source	E. coli/ml
Challenge dosage	410
Filter media #05125	0.02
Filter media #04075	<0.01
Filter media #03105	<0.01
Control carbon #1	140
Control carbon #2	330
Control carbon #3	120

Note: The silver content in the effluent during the 2000-gallon challenge of water ranged from 23 to 48 ppb; the silver content in the effluent used for bacteriological testing was not determined.

The chemical data provided for the 10 units are summarized below:

Sampling Time	ppb Ag
5 gal. challenge	43-52
500 gall. challenge	33-40
After 18-hr. holding	
period	42-48
1200 gal. challenge	21-31
2000 gal. challenge	22 -28

pH of water = 7.4-7.6; temperature = 23-24°C; flow rate; 500 ml/min.

202.0 Recommendations

- Claims supported by data: The requirement to demonstrate that the silver concentration of the effluent water does not exceed 50 ppb after treatment is fulfilled by the chemical data provided.
- 202.2.2 Data not appropriate: The bacteriological data are inappropriate to support a self-sanitizing claim for filter media. To support such a claim, a study must be designed to demonstrate (1) that the filter media does retain bacteria in sufficient number and (2) that the filter media does effectively and significantly reduce the bacterial population retained.
- 202.2.3 Lesser claim the data will support: The data provided suggest inhibition of bacterial growth in water stagnated within the filter media for 10 hours. However, a conclusive evaluation of these data is prohibited because adequate control data and bacteriological—test procedures were not provided.
- Additional data required: To substantiate the pacteriostatic claim for the filter media, the following data should be provided:

 (T) Assays of the bacterial challenge dosage are required both at the beginning of the test and after the 10-hour holding period to ascertain the degree of natural "dieoff" for the bacterial aqueous suspension; (2) Assays of the effluent from the product media and the carbon control are required immediately after the bacterial challenge as well as after the 10-hour holding period to verify the effect of the holding period; and (3) determinations of the silver content in the effluent at these sampling times are required to verify that the bacteriostatic effectiveness of the filter media is based on a silver concentration which is less than 50 ppb. Include bacteriological test procedures with these test results.
- 203.0 Labeling 2) the newtralizer used.

 204.0 Labeling 2) the newtralizer used.

 2) Conc. of Aq in 3 feet units used for backeriological

 The following labeling revisions are required: 4) count procedures for 3 tech

 and 3 control units.
 - Change "Self-sanitizing" to read "bacteriostatic"
 - 2. Change the claim "Prevents the growth of bacteria" to read

Lit Brown (P).

"Inhibits the growth of bacteria."

- 3. Delete "as a sanitizer."
- 4. Provide the necessary calculations to verify that the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

Any collateral literature, such as technical bulletins or brochures, distributed in conjunction with this product must be submitted for review.

Donothy m Portner

Dorothy M. Portner

9/30/75

Efficacy Section
Efficacy and Ecological Effects Branch



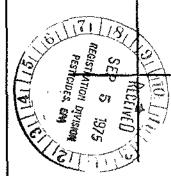
SELF-SANITIZING WATER FILTER MEDIA

- Prevents the growth of bacteria
- · Removes objectionable taste, odor and color

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed contoiner which excludes moisture and chemical fumes.

EPA Reg. No.	EPA Est. No. 35900 PA 01
ACTIVE INGREDIENT METALLIC SLIVER 1.05% INERT INGREDIENT	LOT'NO.
ACTIVATED CARBON98.95 %	NET CONTENTS cu. ft. : Flow rate is not to exceed 15 GPM per cu. ft. of media. Bed depth must be at least
DISPOSAL OF SPENT MEDIA:	twice the diameter. Retain shipping carton and plastic liner for disposing of exhausted filter media with trash.
Another fine product by the manufacturers	of General Ionics Water Conditioning Equipment
IONICS, INCORPORATED Routes	519 & 50, Bridgeville ,Penna.15017



248



P.O. SOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A.C. 412 343-1040 TWX 5106973299

September 3, 1975

AIRMAIL SPECIAL DELIVERY

CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESSEE ONLY

Mr. James H. Banks - PM 33 United States Environmental Protection Agency Disinfectants Branch, Room 321 Registration Division (WH-567) OPP-EPA 401 M Street S.W. Washington, D. C. 20640

Subject: HYGENE

Ionics File Symbol #5900-E

Ionics Application of February 10, 1975

Dear Mr. Banks:

Enclosed with this letter are our test results on "Evaluation of HYGENE Product Media for EPA Registration". This testing procedure was performed in accordance with instructions from Mr. E. F. Brown, Chief - Disinfectants Branch, Environmental Protection Agency.

It is our understanding from our conversations with Mr. Brown that if our test results show that we kill more than 90% of the coliform, our EPA rating would be as a self sanitizer. If we were to kill less than this, we would receive a bacteriostatic rating.

We have also enclosed a copy of the letter we received from you dated July 25, 1975 and received in our office on July 30, 1975. This gave us the guide lines for our testing which was later supplemented by our instructions from Mr. Brown.

This letter also gave us guide lines for our labeling and five copies of our proposed labeling are enclosed.

We respectfully request your urgent evaluation of the enclosures along with our previous data since we are at present under a "Stop Shipment Notice" from your enforcement division.

If there are any questions at all concerning this data, please contact me.

SEP 5 REGISTRATION DIVISION PESTICIDES, EM

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle Enclosures

cc: J. D. Collins



IDNICS, INCORPORATED

P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

September 3, 1975

AIRMAIL SPECIAL DELIVERY

CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESSEE ONLY

Mr. James H. Banks - PM 33
United States Environmental Protection Agency
Disinfectants Branch, Room 321
Registration Division (WH-567)
OPP-EPA
401 M Street S.W.
Washington, D. C. 2064D

Subject: HYGENE

Ionics File Symbol 359D0-E

Ionics Application of February 10, 1975

REGISTRATION DIVISION

PESTICIDES, EPA

Dear Mr. Banks:

Enclosed with this letter are our test results on "Evaluation of HYGENE Product Media for EPA Registration". This testing procedure was performed in accordance with instructions from Mr. E. F. Brown, Chief - Disinfectants Branch, Environmental Protection Agency.

It is our understanding from our conversations with Mr. Brown that if our test results show that we kill more than 90% of the coliform, our EPA rating would be as a self sanitizer. If we were to kill less than this, we would receive a bacteriostatic rating.

We have also enclosed a copy of the letter we received from you dated July 25, 1975 and received in our office on July 3D, 1975. This gave us the guide lines for our testing which was later supplemented by our instructions from Mr. Brown.

This letter also gave us guide lines for our labeling and five copies of our proposed labeling are enclosed.

We respectfully request your urgent evaluation of the enclosures along with our previous data since we are at present under a "Stop Shipment Notice" from your enforcement division.

If there are any questions at all concerning this data, please contact me.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens

WJP:mle Enclosures

cc: J. D. Collins

Vice President



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460 REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

JUL 2 5 1975

Gentlemen:

Subject :

HYGENE

File Symbol 35900-E

Your application of February 10, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

- 1. The data submitted do not support claims of efficacy for this product as a water purifier. Submit chemical and bacteriological data developed in accordance with the procedures outlined in Part VII A and B of the document "Interim Standards for Water Purifier" enclosed herein.
- 2. Submit labeling amended to include only bacteriological efficacy claims delineated in Part VI of this document.
- 3. The labeling submitted must be amended to include mandatory labeling requirements as indicated below:
 - A. On the front panel:
 - 1. An acceptable product name. (The present name is acceptable)
 - 2. The ingredient statement must appear on the front panel, or that part of the label displayed under customary conditions of purchase. Also, the ingredient statement must be clear on a contrasting background, not obscured or crowded.
 - 3. The word "CAUTION" followed by the referenced "Keep Out of Reach of Children" Note: These must appear in proper type size as indicated on the "Front Panel Precautionary Labeling Requirements" enclosure.
 - 4. A statement of net contents, as for example "Net Contents: 1 water purifier unit."

- B. The following may appear elsewhere on the label:
 - 1. The name and address of the registrant.
 - 2. A container disposal statement somewhat as "Wrap spent purifier unit in newspaper and discard with trash."
 - 3. Directions for use or a statement setting forth where such directions may be found such as "See enclosed circular (or leaflet or bulletin) for directions for use."
 - 4. The assigned EPA Reg. No.
 - 5. The EPA Est. No.

oughs

This product may not be lawfully distributed in interstate commerce until it is registered.

Sincerely,

James H. Banks

Product Manager 33

Disinfectants Branch (WH-567)

Enclosure

William of the

REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Gentlemen:

Subject :

HYGENE

File Symbol 35900-E

Your application of February 10, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

- 1. The data submitted do not support claims of efficacy for this product as a water purifier. Submit chemical and bacteriological data developed in accordance with the procedures outlined in Part VII A and B of the document "Interim Standards for Water Purifier" enclosed herein.
- 2. Submit labeling amended to include only becteriologisal efficacy claims delineated in Part VI of this document.
- 3. The labeling submitted must be amended to include mandatory labeling requirements as indicated below:
 - A. On the front panel:
 - 1. An acceptable product name. (The present name is acceptable)
 - The ingredient statement must appear on the front panel, or that part of the label displayed under customary conditions of purchase. Also, the ingredient statement must be clear on a contrasting background, not obscured or crowded.
 - 3. The word "CAUTION" followed by the referenced "Keep Out of Reacheof Children" Note: These must appear in proper type size as indicated on the "Front Panel Precautionary Labeling Requirements" enclosure.
 - 4. A statement of net contents, as for example "Net Contents: 1 water purifier unit."

- B. The following may appear elsewhere on the label:
 - 1. The name and address of the registrant.
 - 2. A container disposal statement somewhat as "Wrap spent purifier unit in newspaper and discard with trash."
 - 3. Directions for use or a statement setting forth where such directions may be found such as "See enclosed circular (or leaflet or bulletin) for directions for use."
 - 4. The essigned KPA Reg. No.
 - 5. The EPA Ret. No.

This product may not be leafully distributed in interstate commerce until it is registered.

Sincerely,

James H. Benks

Product Manager 33

Disinfectants Branch (WH-567)

Enclosure

WH-567:DIS:RGD:md:7-23-75:59040:Rm 321



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460 REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

JUL 2 5 1975

Gentlemen:

Subject :

HYGENE

File Symbol 35900-E

Your application of February 10, 1975

TO THE PARTY OF TH

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

- 1. The data submitted do not support claims of efficacy for this product as a water purifier. Submit chemical and bacteriological data developed in accordance with the procedures outlined in Part VII A and B of the document "Interim Standards for Water Purifier" enclosed herein.
- 2. Submit labeling amended to include only bacteriological efficacy claims delineated in Part VI of this document.
- 3. The labeling submitted must be amended to include mandatory labeling requirements as indicated below:
 - A. On the front panel:
 - 1. An acceptable product name. (The present name is acceptable)
 - 2. The ingredient statement must appear on the front panel, or that part of the label displayed under customary conditions of purchase. Also, the ingredient statement must be clear on a contrasting background, not obscured or crowded.
 - 3. The word "CAUTION" followed by the referenced "Keep Out of Reach of Children" Note: These must appear in proper type size as indicated on the "Front Panel Precautionary Labeling Requirements" enclosure.
 - 4. A statement of net contents, as for example "Net Contents: 1 water purifier unit."



- B. The following may appear alsewhere on the label:
 - 1. The name and address of the registrant.
 - 2. A container disposal statement somewhat as "Wrap spent purifier unit in newspaper and discard with trash."
 - 3. Directions for use or a statement setting forth where such directions may be found such as "See enclosed circular (or leaflet or bulletin) for directions for use."
 - 4. The assigned EPA Reg. No.
 - 5. The EPA Est. No.

ougho

This product may not be lawfully distributed in interstate commerce until it is registered.

Sincerely,

James H. Banks

Product Manager 33

Disinfectants Branch (WH-567)

Enclosure



2-A 2-B 2-C Review under revised Sec. 3 Reg. Yes No
Date of Submission: 1/3-15 Reg/EXP 35400 Petition No. Product Name 199016
Petition Type of Product: I R H F D Type Submission-New Product Old Chem Type Submission-New Product Old Chem
Product Manager (name): Rm# Amended Reg. Substantive Amended Reg. Nonsubstantantive Reviews Needed Rec'd by E. Gross Sent to Reviewer Date Completed Returned to PM
RET
Completeness Review Data Review_ Waiver Reg
Review Labeling
Ger information Schmidde d'in reference to
EREB .
EFFICACY
Completeness Review Data Review Waiver Req.
Review Labeling .
Letter
F&W The state of t
Completeness Review Data Review Waiver Reg
ew Labeling
Lever
ENV. CHEM.
Completeness Review Data Review Waiver Reg
Review Labeling
Letter
Completeness Review Data Review Waiver Reg
Review Labeling
Letter
CHEM BR. Completeness Review Data Review Waiver Reg. Review Labeling
Letter257

	•			
7		-	(
/2.9	2-8 2-6	Review unde	er revised Sec. 3	Reg. Yes }
Date of Submissi	ion: 12-3-75 Rec	g/EXP//#	Peti	tion No.
Product Name # Company Fonce	12 Waler (Pean	er ·		
Type of Product:	· IRHFD	Nev	tition v Product -New Chem	.m
Omnduct Manager	(name): Banks Rn	ype Submission-New	Product Old Cher	in 45
Product miningal,	(name), your	Ame	ended Reg. Substant ended Reg. Nonsubst	tantantive
Reviews Meeded	Rec'd by E. Gross	Sent to Reviewer	Date Completed	Returned to P
RET				
Completeness Rev	view Data Rev	iew Waiver	· Reg	
Review Labeling_			- · ·	
Leuter				
EEEB	-		•	-
EF: VCY				
Co. :teness Rev	view X Data Revi	iewWaiver	^ Reo.	<u> </u>
Review Labeling				
~ -·-	ment on Ti	i. of 12-3	<i>?-25.</i>	
FSW				
-	viewData Revi	iew Waiver	· Rea	
I				
	· · · · · · · · · · · · · · · · · · ·			
E. CHEM.				
	viewData Rev	ies Waiver	- Pog	<u></u>
			vea	
Letter			<u> </u>	
TOX DA.	<u></u>		l	
	view Data Rev	,		
•				<u>,</u>
Letter				
CHEM BR.	Data Pay	l Waiwo	- 15	<u></u>
Completeness Rev Review Labeling	view Data Rev	/iew Walver		258

	SUBMISSION REVIEW RECORD			1.	1. REGISTRATION NUMBER						CACFE	CYCLE 2. PATE A					EGEIVED-		
	SUBI	MISSION	REVIEW RECORD	3	5	9	0	1 -			\ \Z	F	1	10	Z	17	Z	13	
3.	3C!D	PUBLICA	ATION NECESSARY	4.	4. PETITION NO.							5,		EIVE					
		YES	□ NO										10 21/ 25						
6.	6. METHOD OF SUPPORT				PRO	ouc.	T MAN	AGER	_	`		NO.	8.		ECT		, ,		
		2 A [] 20 B 20		16	m	ک	11:	5	and	\$	3 3		MO	°	ÂY	`	/ R	
9.0	DATE	PULLEO	10 DATE PUBLISHED	11.	25	ION	TYPE				14	2998	12		GOIN				
L	9.0ATEPULLED 10 DATE PUBLISHED 3-24-75			1		Su	bm	ىكى	on	. 6	arla.	15 W		MO	٥	AY	,	Y 18	
>0	REVIEW TYPE CODE		REVIEW TYPE	RE	VIEV	VER				FREVI		COM- MENT		ATE F	EVIE	w co	MPLE	TED	
REV SEQ.	# <u>}</u> -0			(1	nitia	ls)						CODE		MQ	0,	AY	`	YR	
L	A	REVIEV	MAST YTLIGAY									<u> </u>						<u> </u>	
	В		CT MÅNAGER TEAM CCY REVIEW																
	C		CT MANAGER TEAM SAFETY REVIEW													L			
	D	PRODUC	CTMANAGER TEAM EN- ENTAL SAFETY REVIEW															L	
	Ε		CT MANAGER TEAM MISSION REYIEW																
	F	PM0000	CT MANAGER														<.		
	G	INTERA	GENCY REFERRAL											1					
	н	соэт-в	ENERIT REVIEW											<u> </u>				: '	
	1	Public	COMMENTS REYIEW											1					
	J	EEE BR EFFICA	ANCH INSECTICIDE CY																
: ^-	к	EEE BR EFFICA	ANCH HERBICIOE											L					
	L	EEE BR EFFICA	ANCH FUNGICIOE CY											L					
	М	EEE BR EFFICA	ANCH RODENTICIOE											L					
X	'n	EEE BR EFFICA	ANCH DISINFECTANT CY	8	M	p	DI	2b /	Por	lower			1	0	2	3	7	<u>3</u>	
1	0	CHEMIS'	TRY BRANCH E CHEMISTRY											L					
	Р		ANCH ENVIRON . CHEMISTRY																
	Q		LOGY BRANCH Safety			,													
	R		ANCH ENVIRON- L SAFETY																
	s																		
	τ						+ 1,											<i>81</i> /	
PRO	DUC	TMANA	GENSIGNATURE	/	m	/_	TYPE	OF PIES	PONSE		بري			`		-/1	:00E		
	C	W)	Longlas for		B	5	1	gu	les	tion	> 70	The	مس	,		4	1	2	
EPA.	Farm	8570-13	(3-78)					<u></u>											

EFE ROPCH REVIEW

DATE: III OUT	IN OTH	IN 10/21/75rr 10/23/75
rish & Wildlife	ENVIROPMENTAL CHEMISTRY	FFFICACY
	· · · · · · · · · · · · · · · · · · ·	
•		
FILE OR RESS. NO.	35900-E`	
PETETION OR 12AP. PETETT NO		
DATE DIV. RECEIVED -		•
DATE OF SUMBISSION	10-14-75	
DATE SUMMISSION ACCEPTED	•	,
THE PRODUCT(S): I,(D), H, F,	N, R, S Bacteriostatic W	ater Filter Media
PRODUCT MER. NO.	33	
PRODUCT NÁTE(S)	Hygene '	
CO-PANY NAME	Ionics, Incorporated	
SUBMISSION FURPOSE	Resubmission with data	
CHEMICAL & FORMULATION	Metallic Silver 1.05%	1

200.0 Introduction

200.1 Use: Bacteriostatic Water Filter Media

200.1.1 Background information: This submission includes information requested in our letter of October 9, 1975.

201.0 Data Summary

201.1 Abstract of test report: The concentration of the artificially contaminated water used to challenge units averaged 410 E. coli per ml; after sitting 2 hours, the concentration of this artificially con-

Abstract of test report: The concentration of the artificially contaminated water used to challenge the units averaged 410 E. coli per ml; after sitting 24 hours, the concentration of this artificially contaminated water also averaged 410 E. coli per ml according to Linda Deans, who was responsible for the testing. No determination was made for the silver content in the effluent which was assayed for bacteriological efficacy. However, since the chemical data provided to demonstrate silver release did not exceed 50 ppb, it will be assumed that the silver concentration in the effluent used in the bacteriological assays also did not exceed 50 ppb.

202.0 Recommendations

202.1 Claims supported by data: The information provided fulfill the request indicated in our letter of October 9, 1975.

203.0 Labeling

Revise the first two paragraphs of the letter to be sent to your customers to read: "This letter is to inform you that Ionics, Incorporated has a bacteriostatic water filter media product, Hygene, EPA Reg. No. 35900-2."

"Hygene has been laboratory tested to demonstrate bacteriostatic activity. The filter media will inhibit the growth of bacteria which is entrapped during the treatment of water."

Dorothy in Portner

Dorothy M. Portner

10/23/75

Efficacy Section
Efficacy and Ecological Effects Branch

			Τ,			EGIET D	ATIO	N NO O	ADE D		CYC	. E	2.		YE D	ECE	DVED	
	SUB!	MISSION REVIEW RECORD	3	5 5	2	D D	-	14 10	1	Z	- 1	-6	<u> </u>	99	2		IVEO	5
3.	3C(D	PUBLICATION NECESSARY		ETITI	ON	NO.		L,			1		5.	⊦ / REC'	EIVE) PM	TEA	M
	_	YE5 1 NO				•							} -	40]		AY	Y	
6.	MET	HOD OF SUPPORT	7. P	RODU	JCT	MANA	SER.				NO).	8. F	ROJ	E CTE	O 8	ETUR	ŧΝ
		2A 🗌 28 💢 2C	Ja	 2101	æ			B	an	5	3	3	├─ ─	10	0,		¥	
9.0	ATE	PULLED 10 DATE PUBLISHED	11. A	CZH	ΝT	YPE					COL	DE	12.	OUT	GOIN	G D	ATE	
		3-24-75	1	/_	C	uh,	m i	65	/жи	/		7		10	0/	·v T	Ÿ	R
		0210	K		<u>ر</u>	40	/ /) I	ربر 	010		(D)	\preceq	<u> </u>	<u>L</u>				
	₩	,	REV	EWE	p.						CO	M	Oρ	TE A	EVIEV	V CD	MPLET	ŒĎ
REV SEQ.	REVIEW TYPE CODE	REVIEW TYPE	C	OCE (tials)		\$IG	NATU	REO	FREVIE	EWER	MEN	Ϋ́	N		ره	٧.	Y	ĸ
	Α	REVIEWABILITY TEAM	X	4	4		46	la		204			0	15		رب	_7	-
	В	PRODUCT MANAGER TEAM EFFICACY REVIEW		10	1		(\leq	$\sqrt{2}$	and C	39		0	L				Ĵ
	С	PRODUCT MANACER TEAM HUMAN SAFETY REVIEW		1					, 		ļ							····
<u>_</u>	D,	PRODUCT MANAGER TEAM EN- VIRONMENTAL SAFETY REVIEW			_									<u> </u>	أـــا	_		
=	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW												<u> </u>			1	
_	F	PRODUCT MANAGER			1		<u> </u>				· 		<u> </u>]		_		
	G.	INTERAGENCY REFERRAL			-			······································		····	ļ		_		.		.]	
	Н	COST-BENEFIT REVIEW			_					 	_			<u>L</u>				
	ı	PUBLIC COMMENTS REVIEW			\downarrow		w.		·		-							
	J	EEE BRANCH INSECTICIDE			#				-		 					-		
 	K	EEE BRANCH NERBICIDE EFFICACY			-										<u></u>	_		
	<u> </u>	EFFICACY EFFICACY EEE BRANCH RODENTICIDE			+		•					-			l	_		
	\mathcal{M}	EFFICACY												L				
	N	EEE BRANCH DISINFECTANT EFFICACY	81)	n P		Dn	Pin	In	نيسا				0	9	3	0	71	_ک
	D	CNEMISTRY BRANCH RESIOUE CNEMISTRY			1						<u> </u>						1	
	Р	EEE BRANCH ENVIRON - MENTAL CHEMISTRY	****		\downarrow			·—.			<u> </u>					_		
	a	TOXICOLOGY BRANCH NUMAN SAFETY		1.	_						ļ	_ 					1	
	R	EEE BRANCH ENVIRON- MENTAL SAFETT		-	-			· · · · · · · · · · · · · · · · · · ·										
	S				1												}	
	• Т																	
PRC	DUC	T MANAGER SIGNATURE			Ti	TYPE OF	RES	PDNS	E							Ç	DDE	
					ļ				•									

Product ingredient source information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

3. . Conditioning Equipment . Custom Fabrication for the Nuclear, Chemical & Food Industries . Heat Transfer Equipment

July 21, 1975



Mr. James H. Banks, Products Manager 33 Disinfectants Branch (WH-567) United States Environmental Protection Agency Registration Division M Street S.W. shington, D. C. 20460

Dear Mr. Banks:

This morning I received a phone call from

■informed me that he had a meeting with EPA in Washington on Friday, July 18, 1975. They informed him that he must list the active and inactive ingredients in his product along with the formulation.

This letter is to inform you that were uses our HYgene in his product and we would allow you to refer to our File No. 35900-E for Hygene for this information. It is my understanding that this information, however, will be kept onfidential.

I hope this gives you the information you need to allow mplete the registration.

If you have any questions on any of this, please feel free to contact

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

me.





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment . Custom Fabrication for the Nuclear, Chemical & Food Industries . Heat Transfer Equipment

Date: February 12,1975

Name of Petitioner: Ionics, Incorporated

Post Office Address: P. O. Box 99; Bridgeville, Penna. 15017

Date: February 12,1975

Name of food additive and proposed use: Hygene - Used as a water purification

media in systems for drinking water purifiers.

Environmental Protection Agency Registration Division WH567 401 M Street, S.W. Washington, DC 20460

Gentlemen:

The undersigned, Ionics, Incorporated, submits this petition pursuant to Section 409 (b) (l) of the Federal Food, Drug, and Cosmetic Act with respect to Hygene Purification Media and Systems for Drinking Water Purifiers.

Attached hereto in triplicate, and constituting a part of this petition, are the following:

- 1. Technical Bulletin Hygene Water Purification Process Description of Material and Design Practice 5/15/73
- 2. Hygene Manufacturing and Quality Control (Manufacturing Procedure and Formulation). Note: This is proprietary information.
- 3. Hygene Quality Control Testing Procedure
- 4. Low Range Silver Test Procedure
- 5. SABRO Laboratory for Bacteriological Analysis of Water-Specification Sheet L 831 R

7"

- 6. Questions & Answers about Hygene Water Purification Process Brochure H-174
- 7. General Ionics Hygene Water Purifier Specification Sheet HYG-10-70
- 8. HYgene Water Purifiers Industrial/Municipal Specification Sheet HYI-672
- 9. (a) Hygene shipping carton label Hygene Water Purification Media (b) Hygene Water Purifier label
- 10. Method for Determining Total Silver Content of HYgene
- Public Health Service Drinking Water Standards Revised 1962
 Pages 8, 52, 53 and 54
- 12. Standard Methods for the Examination of Water and Waste Water by APHA, AWWA, WPCF Pages 309 thru 316, 678 thru 683
- 13. "Basis for Choice of Hyla Silver Disinfecting System for Drinking Fountain, Home, and Small Institutional Supplies, and for Swimming Pool Waters" by Dr. Charles E. Renn of The Johns Hopkins University Note: The name of the product was changed from Hyla to Hygene in 1969.
- 14. "Results of Study to Determine the Comparative Bactericidal Efficiencies of Silver as Silver Nitrate and Silver Activated by the Hyla Process" by Dr. William E. Chesney of The Johns Hopkins University.
- 15. "Report on Bactericidal Effect of Hyla 603-KM at Varying Temperature Levels" by Dr. William E. Chesney of The Johns Hopkins University
- 16. "Performance Record of Experimental Hyla Treatment of Well Water Supply of G. Ward Barstow Residence, Bradshaw, Maryland" by Dr. William E. Chesney of The Johns Hopkins University
- 17. "Effects of Surface Blocking upon Activity of Hyla 603-KM: Methods of Study" by Dr. William E. Chesney of The Johns Hopkins University
- 18. NASA Tech Briefs No. B68-10555 and TSP71-10278
- 19. "Notes on Tolerance of Humans, to Ingested Silver" by Dr. Charles E. Renn, The Johns Hopkins University
- 20. Addendum to A. Description of the Hyla Process Question: Has Silver a toxic effect on the human organism? by Dr. E. Hofer, Geneva, January 18/54

- 21. "Preliminary Report on the Installation of a Hyla Water Purification System U.S. Navy Preventive Medicine Unit No. Two"
- 22. Four Years Bacteriological Ship's Report 1956-1960
- 23. "Silver Cleans up Polluted Water" The Silver Institute Letter, Volume III, Number 7 July-August 1973
- 24. "The Story of Silver in Medicine" by Dr. Harry Margraf Gold & Silver Newsletter, September 1974
- 25. DODUCO letter of November 16, 1973 with report on experiences with a Hygene Water Purifier HY-45
- 26. Stage Coach Motel letter of August 8, 1971 with Bacteriological Reports from The Commonwealth of Pennsylvania, Department of Health on Hygene Water Purifier
- 27. United Engineers and Construction information on Hygene Water Purification System.
- 28. Fonderlac Country Club letter concerning HYgene system with Bacteriological Reports from County Health Department
- 29. NUS Corp., C. W. Rice Division Laboratory Report 5/28/74 on the Arnold Industries Hygene Water Purifier
- 30. NUS Corp., C. W. Rice Division Laboratory Report 6/6/74 on the Pure Water Maker Water Purifier manufactured by Water Purification Technology
- 31. NUS Corp., C. W. Rice Division Laboratory Report 6/19/74 on the Pure Water Maker Water Purifier manufactured by Water Purification Technology

In addition to the above enclosures, we would like to offer these comments with respect to requested information in the order asked in Chapter 1 - Food and Drug Administration, § 121.51 Petitions proposing regulations for food additives.

Α.

- Our Enclosure No. I describes the physical properties of HYgene including the chemical identity and composition as well as its biological properties and intended use which is for the purification of bacteriologically contaminated water.
- 2. The step by step method of manufacture of HYgene is in our Enclosure No. 2. (This is proprietary information of Ionics, Incorporated). Our quality control of the finished product is Enclosure No. 3 and also Enclosure No. 10. Enclosure No. 3 method is used on every HYgene lot manufactured. Enclosure No. 10 is a procedure periodically used by an outside laboratory.
- 3. Bacteriological analyses used in our quality control are performed by the SABRO Laboratory (Enclosure No. 5) which uses the membrance filter technique. This procedure is in accordance with <u>Standard Methods for the Examination of Water and Wastewater</u> published jointly by the APHA, AWWA, and WPCF. See Enclosure No. 12, Pages 678 thru 683.
- 4. Silver is determined in our laboratory by procedure found in Enclosure No. 4. In addition to this colormetric procedure, we also periodically send samples to an outside laboratory for silver analysis by the Atomic Absorption (AA) method.

The AA method is very accurate in the range of 10 to 50 ppb and can be run by any reasonably well equipped lab. We have this AA equipment at our Watertown, Massachusetts lab. See Enclosure No. 12, Pages 309 thru 316.

5. The list of chemicals and quantities used in the manufacture of our Hygene product can be found on Page 5 of Enclosure No. 2. After undergoing chemical changes throughout the manufacturing procedure, the finished product contains:

Active Ingredient - Metallic Silver 1.05% Inert Ingredient - Activated Carbon 98.95%

Total Ingredients 100.00%



A. continued

6. Hygene has an indefinite shelf life when stored in our shipping containers and in accordance with our labeling instructions (Enclosure No. 9) which states that is should be stored in closed container which excludes moisture and chemical fumes. Our shipping container is of heavy cardboard carton construction, lined with sealed, sanitary polyethylene bag.

В.

- 1. The Hygene media shipping carton label is Enclosure No. 9 (a) and the Hygene unit label is 9 (b). We are adding to these labels the active and inert ingredients with percentages as stated above under A-5.
- 2. The human tolerance limitation for silver in drinking water is 50 parts per billion (ppb) as indicated in Enclosure No. 11, Page 8 of the <u>Public Health Service Drinking Water Standards</u>. Also, in this same book, Pages 52, 53 and 54 discuss, a) studies of the metabolism of silver from intragastric intake in rats, b) a study of the toxicologic effects of silver added to drinking water of rats, and c) a study of the resorption of silver through human skin.

NASA Tech Brief 68-10555, Enclosure No. 18 states "Silver Ions in concentrations of 50 to 100 ppb which are nontoxic when ingested, have been recognized for many years as an effective bactericide.

c.

1. As water passes through a layer or bed of our HYgene product, silver is released into the effluent water under the standard limitations of 50 ppb. In addition to the silver being under these limitations, it is also in sufficient quantity to have the intended bacteriological effect on pathogenic bateria. Laboratory testing in regard to this can be found in Enclosure Nos. 14, 15, 17, 29, 30 and 31. Actual field test data can be found in Enclosure Nos. 16, 21, 22, 25, 26 and 28.

Additionally, Ionics installed a 100,000 GPD Hygene potable water system (Enclosure No. 27) at The United Engineers and Constructors Jobsite of the Pennsylvania Power and Light Company, Martins Creek Steam Electric Station, Martins Creek, Pennsylvania, in September, 1971. This system is designed to produce potable water from Delaware River water for the approximately 1200 construction workers on site and has been in continuous operation since 1971, producing in excess of 32,000,000 gallons of potable water since startup. This installation was made and continues to operate under authority of the Pennsylvania Department of Health and Environmental Engineering.

D.

 Methods used to determine the amount of silver in HYgene systems effluent are as discussed under A-4 of this letter. Consistent accurate results can be achieved by any properly equipped testing laboratory.

E.

1. Investigations with respect to the safety of the use of HYgene were conducted under the direction of Dr. Charles E. Renn of The Johns Hopkins University, Department of Sanitary Engineering and Water Resources. See Enclosure No. 19 regarding tolerance of humans to ingested silver in the range effected by the HYgene process. In this regard, also see comments from Dr. Er Hofer in Enclosure No. 20.

This is also answered by Enclosure No. 11.

F.

1. Tolerances and limitations of silver in drinking water are covered by <u>Public Health Service Standard Drinking Water Standards</u>. Enclosure No. 11.

G.

1. Not applicable

H.

 Effluent from manufacturing process disposed to drain contains common chemicals as listed in Enclosure No. 2 in a dilute form.

H. continued

2. In the ultimate use as drinking water, there are no ill effects as indicated in Part B-2 of this letter concerning toxicity of silver. Water from the HYgene system effluent going to drain or waste is also harmless since it contains no more than 50 ppb silver.

Please also note Dr. Harry Margraf's article (Enclosure No. 24) in the Gold & Silver Newsletter, "The Story of Silver in Medicine". On Page 4, Dr. Margraf states, "Silver filters are used to transform polluted waste into drinking water. It's more effective and safer than chlorine, ozone or ultraviolet radiation." Also, he says, "I believe that in the not-to-distant future silver compounds will become the standard method for purifying the public water supply. Silver compounds will play an important role in pollution control."

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

W. J. Polens Vice President

WJP/no

Enclosure

STATEMENT OF OFFER TO PAY AND METHOD OF SUPPORT

SUBJECT:

(Name of Pesticide Product) HYgenetm (EPA Registration Number or File Symbol)

(Date of Application) 2/10/75



- 1. I hereby offer to pay reasonable compensation to the extent provided under Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the interim policy statement published in the Federal Register on November 19, 1973, for use of any test data, which had been submitted to the Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972, and which may be used in support of the registration application for the subject pesticide.
- 2. The method of support to be used in the review of this application is as follows: (list or check one only)
 - a. ALL OF THE REQUIRED SUPPORTING DATA IS ATTACHED.

 (Only the actual data submitted is to be used in the evaluation of this application.)
 - b. ALL OF THE REQUIRED SUPPORTING DATA IS BEING SUBMITTED BY REFERENCE.

 (Only the specific references submitted are to be used in the evaluation of this application. Any combination of data and references should be submitted as 2.b. with the data listed with the reference.)
 - C. PROCEED ON THE BASIS OF ESTABLISHED USE PATTERNS.

 (Any application for which the applicant desires the Agency to use any or all available information in addition to what is provided by the applicant must proceed under 2.c. Applications containing data for specific uses or references for part of the required information, but requiring additional information already on file with the Agency to be complete, must proceed under 2.c.

(Signature of Applicant)

(Name of Applicant) W. J. Polens

(Title of Applicant) Vice President, Ionics, Inc.; P.O. Box 99; Bridgeville, Pa. 15017

(This statement must be signed by an authorized representative of the applicant.)



BACTERIOSTATIC WATER FILTER MEDIA

Inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed cantainer which excludes moisture and chemical fumes.

EPA Reg. No. 35900-2	EPA Est. No. 35900 PA 01
ACTIVE INGREDIENT	
METALLIC SLIVER 1.05% INERT INGREDIENT	LOT NO.
ACTIVATED CARBON 98.95 %	NET CONTENTS ou ft
DIRECTIONS FOR USE:	NET CONTENTS cu. ft. Flow rate is not to exceed 15 GPM per
	cu.ft. of media. Bed depth must be at least
DISPOSAL OF SPENT MEDIA:	twice the diometer. Retain shipping carton and plastic liner for
	disposing of exhausted filter media with trash.
Another fine product by the manufacturers	of General lanics Water Conditioning Equipment
IONICS, INCORPORATED Routes	519 & 50, Bridgeville ,Penna.15017

TECHNICAL BULLETIN





HYGENETM WATER PURIFICATION PROCESS DESCRIPTION OF MATERIAL AND DESIGN PRACTICE

I. DISINFECTION WITH SILVER

The use of silver in the disinfection of water supplies has long been recognized as an established technique. The principle of the HygeneTM process is as follows. Silver ions absorbed on sponge silver metal is deposited on an inert carrier. Activated carbon of high surface area has been found to be an excellent carrier and it is the base of HygeneTM. The silver is deposited in an oligodynamic or finely divided form in such a way that the solubility is limited to meter trace quantities. Therefore, contaminated water, contacting the silver impregnated carbon, will dissolve or release very minute quantities of silver in the range of 25 to 40 parts per billion. HygeneTM is an effective disinfecting material against pathogenic intestinal organisms found in water. These include the germs that cause typhoid fever, dysentery, cholera, diarrhea and other such diseases. HYgeneTM will purify any water which is "bacteriologically acceptable for treatment" as defined in the United States Public Health Service Manual, RECOMMENDED WATER - SANITATION PRACTICE. In addition to its purifying qualities, HYgeneTM also filters the water and removes taste, odor and color from it.

II. HYGENETM RESEARCH

A major part of research and development investigation on the behavior of this media was carried out at The Johns Hopkins University Department of Sanitary Engineering under the direction of Dr. Charles E. Renn. All data included herein can be verified by accomplishments of this research program.

III. PHYSICAL PROPERTIES

The physical characteristics of HYgeneTM are comparable to those of activated carbon substrate upon which a silver salt of complex chemical structure coating is deposited. Addition of silver to the mass does not measurably alter the density of the parent carbon. The physical absorption capacity of the carbon is decreased not more than 2% by the presence of silver.

IV. DESIGN PRACTICE

All HYgeneTM installations made under the supervision of Ionics, Inc. have had a minimum bed contact time of one minute. Performance data has shown this to be adequate. The void space of the bed has been determined to be 40% and is used in all calculations. Under normal or average operating conditions, HygeneTM material can be expected to treat 750,000 gallons of raw water per cubic foot. Equipment design is predicted on flow rate of 3 gallons per minute per cubic foot of material with the height of the filter bed at least twice the diameter of the filter. Installations are usually rated to give a minimum bed life of two years. To provide maximum residual kill, a storage reservoir following the HygeneTM contact bed is recommended where bacteria count of water is excessively high or where demand flow rates are beyond limits. Removal of protective suspended solids is necessary for

VIV. DESIGN PRACTICE (cont'd)

reliable chemical disinfection by any known agent. For optimum performance and long life of HYgeneTM material, the removal of all possible solids prior to the contact bed is therefore desirable. Turbid waters may be clarified by settling, coagulation and settling or by fine filtration. Naturally clarified sources may require no pretreatment, though their inclusion is recommended to insure removal of cysts and larger waterborne intestinal parasites.

V. FIELD CONTROL



A. Bacteriological Test Kit

For an expedient method of measuring the bacteria content of the effluent supply, Ionics manufactures and markets the SABRO Portable Laboratory for bacteriological analysis of water. This unit was developed at The Johns Hopkins University by Dr. Charles E. Renn under a SABRO Fellowship Program. For further information on SABRO, contact Ionics, Incorporated at Bridgeville, Pennsylvania.

B. Silver Test Kit

To determine the silver concentration of treated water, Ionics recommends the use of LaMotte Chemical Company's Low Range Silver Test Kit. This unit is available from Ionics or LaMotte Chemical Company in Chestertown, Maryland.

VI. LABORATORY FACILITIES

Ionics laboratory equipment and technicians are available for complete chemical and bacteriological analysis. Samples of suspicious or problem

VI. LABORATORY FACILITIES (cont'd)

waters as well as treated water samples for quality control check may be sent to our laboratory for a complete analysis. Sampling bottles and recommended technique for collection of water samples are available at lonics.

VII. RAW WATER CONDITIONS

For reliable operation of the HYgeneTM system, the following conditions are necessary:



B. <u>Sulfates</u>: 2,000 ppm maximum

C. <u>Iron</u>: 0.2 ppm maximum. Most raw waters high in iron content can be pretreated for its removal before HYgeneTM.

D. Hydrogen Sulfide: Sulfide may limit the life of HYgeneTM and its removal is therefore recommended before HYgeneTM treatment.

E. <u>Color</u>: 20 maximum. Color is used here to indicate high concentrations of extracted organic matter in water. If color exceeds this value, samples should be performance tested to determine the necessary equipment design required.

F. pH: 5.0 to 8.5

G. Temperature: 400 F to 850 F

VIII. COMMERCIAL INFORMATION

Mesh Size: 12 x 30 U.S. Sieve Series

Weight: 30 lbs. net per cubic foot

Packaging: 1 cu.ft. Fiber Drum or 200 lbs. (6.67 cu.ft.) Fiber Drum

Shipping Point: Bridgeville, Pennsylvania

							·····		-A 71			7			***********		
١,,	1014	SSION REVIEW RECORD	 			EGISTRA	TION III		力之		виіs» Он		OAT	re Rec	ELVE	£	_{
1 3	DDWI		, ,	COM		' NO.		PRODUCT	NO.	CC	OE	YE	AR	MONT	H	YAO	
			; 4	3 5	9	00	- 6	100	OF	-		ריו	3	100		آ [ح	7
AC	TION	TYPE		ODUC	TMA	NAGER	/		·····	1		P	LOR	ECTED	RET	URN	4
		CODE	•							C	OE	 			·····		긕
		ļ 	ᅱ							<u> </u>	1	_ V €	AR	MONT	14	OAY	
L										2	12	l	l				- 1
NE	W CN	EMICAL NEW MIXTURE SI	GNIFI	CANT	NEW	USE	,						Ou.	TGOING	DAT	E	٦
1 -	TYE	9 TYES					1	PETITION	NUMBE	P			AR	MONT		DAY	ᅱ
¹~			□ Y	EB		NO	 	100		1		1		- MON-	~ }-	~~ -	-4
	1	NO LEPRO					<u> </u>	5 7	50	12	17	<u> </u>	<u>L</u>		L_		
51 G	NIFIC	TANT NEW USE F.R. PUBLICAT	10N C	DATE		E EXCLU		F.R. PUI	BLICATIO	O MC	ATE	3 C	D PL	BFICY	TION.	REQ	i
ĮF.₽	i. NUM	MER YEAR MONT	н :	DAY	r.m	NUMBER A	~	YEAR	MONTH		AY	re	3 F E	·		NO.	ı
			4-					772	03	0	IZC	\		•	·	NO	-
 									017	-	IZ.	<u> </u>					4
1	5		R	EVIEW	ER	,				l c	OM-	DAT	TE RE	VIEWC	OMPL	ETED	, [
٦٨	REVIE TYPE CODE	REVIEW TYPE	ł	COOE		SIG	NATURE	OF REVIE	WER	-	ENT	YE	AR	MONT	rN	DAY	٦
E S	ώ×ο		10	inilial	•)					C	POE		Γ	T-		7	ᅥ
20	α÷υ							<u> </u>		 -			L				
1	١. ١		1.5	- A		11.4	4 []	[[]	7	7)	_		٠ . س ا	.		_]
1	A	REVIEWABILITY TEAM	U	17		307 -	4. <i>(</i> 4.	A STATE OF THE STA	~	/6		/	4	0	/ / (سواح	7
—	† -							 U	-1	1	*	<u> </u>	Ĺ				ᅥ
	B :	INSECTICIDE EFFICACY		1 1	:			•		1	f	1		1	- {	1	ļ
<u></u>	ļ		<u> </u>							!	1	!	Ĺ				╝
i	С	GEBBICIOS PERIOS		_			_			l				,	İ	-	1
1	•	HERBICIOE EFFICACY	1	1						ĺ	1		1	1		1	1
	 					····	~~~			 	1		L	 			4
1	ם	FUNGICIOE EFFICACY		, ,	-					l		ĺ			1		1
	L										<u>L</u>		<u> </u>				
			7									<u> </u>		i	T		٦
1	E	RODENTICIOE EFFICACY	١.	.1 1			_	_		! .		l	ı	ـ ئىرا	_	_1	.
_	ļ		12	7		2,2)				-4					74/	<i>4</i>	4
	ا ــ ا		No.	//16	T.	NO.	1	ronc	9	14	Ψ	\ \(\sigma^{\cdot}	ا کِ		45		-
ľ	F	DISINFECTANT EFFICACY		l W	U 1	\mathcal{U} /	Buch	سر را		YO.	Ye !	7	(01	/\ 7	22	. 1
 	-			$-\mathcal{O}_{-}$	7	*1 -/ -/	ACTIVE S	<u> </u>			-	-					ᅥ
1	G					(/	/							١.	1		1
		RESIOUE CHEMISTRY		_[]		•							<u> </u>	l J			.]
					٠.										$\neg \vdash$		7
1	H	ENYIRONMENTAL CHEMISTS	Y	1 1						ł	1		1			1	- [
<u></u>			4							 	L	<u> </u>	L				4
1	Ι.Ι) ^		120	L			A	P)				ᆔᇎ	<u> </u>	-
		HUMAN SAFETY		u Ui		W ()	De si	12		///	6	7	1)	01/	/ 2	12	? i
	 	·	┨—		7-1	7	V-021	~```		<u> </u>	/	_					₹
ļ.	J	F110180011711741 64F871	1		'	()		0		!		١.,		١.			-1
	"	ENVIRONMENTAL SAFETY			ŀ					ļ]				1	1	Į
			1							<u> </u>	·						٦
] K	INTERAGENCY REFERMAL	1	ŧ 1						l	ı	l	l	l ı		ı	- 1
				لــــــــــــــــــــــــــــــــــــــ						<u> </u>	<u>l</u>		L				┛
1	١.		1							l					- 1		- (
l	L	COST-BENEFIT REVIEW	1							l			ĺ		1		į
—				السسان							I	-	Ļ	[-	ᅱ
ŀ	м	M(1=) 6 6 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	İ		l					l	•						I
1	^m	PUBLIC COMMENTS REYIEN	1			·				L		L	_			_]	
			\top	0 -		~		<u>"</u>	,			<u> </u>					٦
1	N	PRODUCT MANAGER TEAM	1	4/				ruglo	, 5 O	1	IA	フ	15	0	フー′	クロマ	1
<u> </u>			_/	اكار	<u> </u>		1	100/0	<u>. </u>	~_						<u>رسو۔</u>	4
l	٥				1	•		ممس			.				İ		į
	"	PRODUCT MANAGER	i	1	1						1						ļ
\vdash	 		-			·······							L		+		┪
1	P	PRODUCT BRANCH CHIEF		1 1	ŀ					1	.	(ı İ	1	ŀ	1	Í
<u></u>				11	<u> </u>						<u> </u>	<u> </u>	<u> </u>				_]
	_		1														٦
1	Q	SCIENCE PEER REYIEW	1	į l						i	1			1		1	-
—							····		 	ļ	L	ļ	<u>L</u>			_نبلب	_
	R				ł						. ,						ļ
ĺ	^	REGISTRATION OFFICER	1]]	-			4.		İ]					ł	į
1							, -, +	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	· ·······	 	•	 	L	L	+		ᅥ
	S	SCIENCE OFFICER	1	4 1	- 1	•					,		,			1	-
L	ĽĪ									L			الللا				
			T							I		<u> </u>			丁		٦
	T	DIVISION DIRECTOR	1	1 1	1						۱. ا			1	1	i	
_	لـــــا			┸		TV2			,	<u> </u>	اا		ــــــــــــــــــــــــــــــــــــــ	L			
"E	MBE	L "PUEEEO" (3210) A	R	(C)	- 1	TYPE OF				****						ONSE	
1				ン	1		6	Zon		2				ì	_co	DE	_1
l		MAP 0 7 1975					~)~ (A.On	banker	T.					4-	. K	1
<u></u>				***************************************					~ 						<u>_</u> _		<u>i</u>

EPA Hq Form 8570-13 (12-74)

278

Public Health Service Drinking Water Standards Revised 1962



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

Washington 25, D.C.

5.22 The presence of the following substances in excess of the concentrations listed shall constitute grounds for rejection of the supply:

Bubelance		ntrollon ng/1
Arsenic (As)	_	0.03
Barium (Ba)		1.0
Cadmium (Cd)	- ,	0.01
Chromium (Hexavaleat) (Cr **)		0. 05
Cyanide (CN)		0. 2
Fluoride (F)	(See	5.23)
Lead (Pb)	.~	0.05
Seienlum (Se)		0.01
Sliver (Ag)	*	0.05

5.23 Fluoride.—When fluoride is naturally present in drinking water, the concentration should not average more than the appropriate upper limit in Table I. Presence of fluoride in average concentrations greater than two times the optimum values in Table I shall constitute grounds for rejection of the supply.

Where fluoridation (supplementation of fluoride in drinking water) is practiced, the average fluoride concentration shall be kept within the upper and lower control limits in Table I.

TABLE 1.

Annual average of maximum daily air temperatures t	Recomm Fluorida	Recommended control limits— Fluorida concentrations in mg/l							
	Lower	Optimum	Upper						
80.0-53.7. \$3.8-58.3. 88.4-63.9. 83.9-70.8. 70.7-79.2. 79.3-90.5.	0.9 0.8 0.8 0.7 0.) 0.6	1-2 1-1 1-0 6.0 0.8 0.7	1.7 1.5 1.2 1.2 1.0 0.8						

I Based on temperature data obtained for a minimum of five years.

In addition to the sampling required by paragraph 5.1 above, fluoridated and defluoridated supplies shall be sampled with sufficient frequency to determine that the desired fluoride concentration is maintained.

6. RADIOACTIVITY

6.1 Sampling.

6.11 The frequency of sampling and analysis for radioactivity shall be determined by the Reporting Agency and the Certifying Authority after consideration of the likelihood of significant amounts being present. Where concentrations of Razze or Sreemay vary considerably, quarterly samples composited over a period of three months are recommended. Samples for determina-

SELENIUM

The presence of selenium in water has heretofore been a matter of regional importance (1). The fact that it is now recognized as being toxic to both man and animals makes it essential that limits be set for all water intended for human consumption.

Selenium is known to produce "alkali disease" in cattle, and its effects, like those of arsenic, may be permanent (1,2). Recent reports indicate also that selenium may increase the incidence of dental caries in man (3). Of greater importance in limiting the concentration of selenium is its potential carrinogenicity (4). Rats fed a diet containing varying concentrations of sclenium (3 to 40 mg/1) showed toxic effects at all levels, the outstanding pathologic lesion being hepatic cell tumors.

From very limited information (5) concentrations of selenium in water considered safe for man have been found toxic for fish.

In view of the potential seriousness of above reported effects, it is recommended that the limits for selenium be lowered from its present value of 0.05 mg/1 to 0.01 mg/1 and concentrations in excess of this lower value be used as grounds for rejection of the supply.

LITERATURE CITATIONS

- Dudley, H. G. Toxicology of selenium: I. A study of the distribulion of selenium in acute and chronic coses of selectium poisoning. Am. J. Hyg. 23: pp. 169-186 (1936).
- Drill, V. A. Pharmacology in Medicine. Ed. 2., New York, N.Y., McGraw-Hill, 1958, pp. 794-795.
- Hadilmarkos, D. M., and Bonhorst, C. W. The truce element sclealum and its influence on dental caries susceptibility. J. Pediat. 52: pp. 274-278 (1958).
- Fitzhugh, O. G., Nelson, A. A., and Bilss, E. I. The chronic oral toxicity of selectium. J. Pharm. Exp. Thec. 80: pp. 280-299 11944).
- Ellis, M. M. Pollution and aquatic life. Am. Wildlife 26: pp. 38, 45-46 (1937).

SILVER

The need to set a water standard for silver (Ag) arises from its intentional addition to waters for disinfection. The chief effect of silver in the body is cosmetic, which consists of a permanent bluegrey discoloration of the skin, eyes, and mucous membranes which is as unsightly and disturbing to the observer as to the victim. The amount of colloidal silver required to produce this condition (argyria, argyresis), and which would serve as a basis of determining the water standard, is not known, but the amount of silver from injected Ag-arsphenamine, which produces argyria is precisely known. This value is any amount greater than 1 gram of silver, 8g Ag-arsphenamine in an adult (1, 2).

From a review (2) of more than 200 cases of argyria, the following additional facts were derived. Most common salts of silver produce argyria when taken by mouth or by injection. There is a long-delayed appearance of discoloration. No case has been uncovered that has resulted from an idiosyncrasy to silver. There was, however, considerable variability in predisposition to argyria; the cause of this is unknown but individuals concurrently receiving bismuth medication developed argyria more readily. Although there is no evidence that gradual deposition of silver in the body produces any significant alteration in physiologic function, authorities are of the opinion that occasional mild systemic effects from silver may have been overshadowed by the striking external changes. In this connection, there is a report (3) of implanted silver amalgams resulting in localized argyria restricted to the elastic fibers and capillaries. The histopathologic reaction resembled a blue nevus simulating a neoplasm with filamentous structures and globular masses. Silver affinity for elastic fibers had been noted a half-century earlier (5).

A study (5) of the metabolism of silver from intragastric intake in the rat using radio-silver in carrier-free tracer amounts showed absorption to be less than 0.1-0.2 percent of the silver administered; but this evidence is inconclusive because of the rapid elimination of silver when given in carrior-free amounts. Further study indicated, however, that silver is primarily excreted by the liver. This would be particularly true if the silver is in colloidal form. Silver in the body is transported chiefly by the blood stream in which the plusma proteins and the red cells carry practically all of it in extremely, labile combinations. The half-time of small amounts of silver in the blood stream of the rat was about 1 hour. A later report (6), using the spectrographic method on normal human blood, showed silver unmistakably in the red blood cell and questionably in the red cell ghosts and in the plasma. Once silver is fixed in the tissues, however, negligible excretion occurs in the urine (7).

A study (8) of the toxicologic effects of silver added to drinking

water of rats at concentrations up to 1,000 ug/1 (nature of the silver salt unstated) showed pathologic changes in kidneys, liver, and spleen

at 400, 700, and 1,000 ug/1.

A study (9) of the reserption of silver through human skin using radio-silver Agun has shown none passing the dermal barrier from either solution (2 percent AgNO₂) or ointment, within limits of experimental error (±2 percent). This would indicate no significant addition of silver to the body from bathing waters treated with silver.

Great uncertainty, however, currently surrounds any evaluation of the amount of silver introduced into the body when silver-treated water is used for culinary purposes. It is reasonable to assume that vegetables belonging to the family Brassicaccae, such as cabbage, turnip, cauliflower, and onion, would combine with residual silver in the cooking weter. The silver content of several liters of water could thus be ingested.

Despite these uncertainties and the present lack of appropriate drinking water studies, it is possible to derive a tentative drinking water standard for silver by using silver deposited in excess of 1g in the integument of the body as an end point that must not be exceeded. Assuming that all silver ingested is deposited in the integument, it is readily calculated that 10 ug/1 could be ingested for a lifetime before 1g silver it attained from 2 liters water intake per day; 50 ug/1 silver could be ingested approximately 27 years without exceeding silver deposition of 1g.

Because of the evidence (7) that silver, once absorbed, is held indefinitely in tissues, particularly the skin, without evident loss through usual channels of climination or reduction by transmigration to other body sites; and because of the probable increased absorbability of silver as silver-bound sulfur components of food cooked in silver-treated waters, the intake for which absorption was reported in 1940 to amount to 60-80 ug per day (10); and because of the above calculation, a concentration in excess of 50 ug/1 is grounds for rejection of the supply.

LITERATURE CITATIONS

- 1. Hill, W. B., and Pillsbury, D. M. Argyrin. The pharmacology of eliver. Baltimore, Md., Williams & Wilkins, 1939, 172 pp.
- Ibid., Argyria Investigotion—Toxicologic Properties of Silver, Am. Silver Producers Res. Proj. Report. Appendix II (1957).
- Bell, C. D., Cookey, D. B., and Nickel, W. R. Ansalgam totoo-localized argyrln. A.M.A. Arch. Derm. Syph. 60: pp. 523-525 (1952).
- Joseph, M., and Van Deventer, J. B., Allas of Cumneous Morbld Histology. W. T. Kliner & Co., Chicago, 1906.
- Scott, K. G., and Hamilton, J. G. The metabolism of silver in the rat with radiosilver used as indicator. U. of Cal. Publ. in Pharm. 2: pp. 241-262 (1950).
- Wyckoff, R. C., and Hunter, F. R. Spectrographic analysis of human blood. Arch. Blochem. 63: pp. 454–460 (1956).
- Aub, J. C., and Fairboll, L. T. Exerction of silver in urine. J.A.M.A. 118: p. 310 (1942).
- 8. Just, J., and Szatolis, A. Germicidal properties of silver in water. J. Am. Water Works A. 28: pp. 492-506, April 1936.
- Norgaard, O. Huvestigations with Rudio Ag ¹¹¹ tato the resorption of stiver through human skin. Acls Dermulovener 34: pp. 415-419 (1954).
- Kehoe, R. A., Cholak, J., and Story, R. V. Mangonese, lend, tin, copper and aliver in normal biological material. J. Nutr. 20; pp. 85-98 (1940).

FATC 650 76 TO THE PLNNSYLVANIA 18017 TELEPHONE 544.

June 25, 1971

United Engineers and Constructors P. O. Box 231R Martins Creek, Pennsylvania 18063

Attention: Mr. William Homeyer Piping Superintendent

Ref: Hygene® Water Purification System for PP&L Co., Martins Creek Steam Plant

Gentlemen:

On June 24, 1971, a meeting was held in the Reading, Pennsylvania district offices of the Pennsylvania Dept. of Health and Environmental Engineering to discuss the Hygene® water purification system proposed for the above referenced installation.

Attending:

Messers Kuder, Parks, Becker and Darrall, Pennsylvania Dept. of Health & Environmental Engineering, Reading

Mr. Paul Zimmerman, Department of Environmental Resources, Harrisburg

Messers Polens and Schmidt, Ionics, Inc., Bridgeville, Pa.

The water system for the construction site will be classified as a "semi-public" system as opposed to a "public" system. This is a very important differentiation since a "public" supply would require submission of an application for Public Water Supply Form H711.513 to the State for approval. Mr. Kuder

lutio 24, 33...

W.T. & Homeyer Piping Superintendent

144.

remarked that if this were the case, it would take several months to pass on the acceptability of the system due to the current heavy backlog of applications. It is very important that the proposed water system be specified as "semi-public" which requires that the system distribution be totally within the confines of the construction site, not available to the general public.

With this stipulation met, United Engineers should submit plans for the complete water treatment and distribution system to:

Penna. Dept. of Health & Environmental Engineering 401 Buttonwood Street Reading, Pennsylvania 19602 Att: Mr. Robert Becker

Mr. Becker estimates, that if the submitted information is complete, he will require one week to ten days for approval. The State will monitor system performance after startup, by testing both silver residual and coliform count. We have furnished a Hach low range silver field test kit to Mr. Becker for this purpose. In addition we have furnished a copy of our proposal to Mr. Becker and a binder containing complete specifications and documentation on Hygene® for their files.

If we can assist you in preparing the submission data, please feel free to contact us.

Very truly yours,

IONICS, INCORPORATED Bridgeville

R. C. Schmidt, Sales Manager

RCS:blf

5 FOR I	RELEASE	
		Additional discountry of the second
ed for	Ionics, Incorporated	West
CG O	Dux 99	Sin in
	Bridgeville, Fa. 15027	
re inform	nation contact A. E. Daniell	THE PARTY OF
	Phone: 412/343-1040	bur carrow of need to commence the season we had

SILVER DISTRIFFCTANT SYSTEM EFFICIENTLY PURIFIES WELL WATER ODOR-FREE AT 100,000 GALLOHS/DAY



Engineers & Constructors for a Hygene water purification plant that will turn well water into potable drinking water in excess of 100,000 gallons per day. The installation of the treatment facility is located in Martins Creek, Pennsylvania where United Engineers is constructing a new power plant for Pennsylvania Power & Light Company.

The HYgene water purifier is a silver disinfectant system that will purify any water which is bacteriologically acceptable for treatment as defined by the United States Department of Health Service Manual. It is particularly effective as a disinfecting material against pathogenic intestinal organisms found in water, including germs that cause typhoid fever, dysentery, cholera or diarrhea.

In addition to its purifying qualities, Higene units filter the water and remove objectionable taste, odor and color without the use of chlorine or other chemicals. The taste problem of chlorinated water has been an increasing concern for field superintendents in the construction and related industries as job-site working crews object more and more strenuously to the

unpleasant tacte of chemically treated water.

The silver purification system was chosen because it is also simple to operate and economical to maintain. The effluent is unaffected by exposure to light or increased temperature. A periodic backwash keeps the system functioning. Ionics' Sabro (R) test kit, employing the membrane filter technique, is used to provide an accurate and rapid bacteriological analysis of the water.

Contact Ionics, Incorporated, Bridgeville, Pa. 15017 for more information on Hygene silver disinfectant systems that are available in commercial sizes for resorts, restaurants, real estate developments, service stations, oil and mining camps and ranches.

Box 145 Mt. Bethel Pa. 18343

February 10, 1975 -

To Whom It May Concern:

In the spring of 1971 I was instrumental in the decision of our company to use a General Ionics hater Treatment Plant for our construction project at Martins Creek Pennsylvania.

We enticipated a total force of over 1200 people at peak use with consumption rates of over 200 G.P.M. during peak hours.

Our water was well water, known to be contaminated beyond allowable lits, but of low turbidity. A silver impregnated Carbon Filter used. Fully automated low maintenance operation was a requirement that had to be met.

Laily testing for bacteria was conducted furing the first few months of operation as well as testing for silver content. Later these tests were reduced in frequency. We are pleased to state that at no time was any evidence of bacteria found.

This plant has more then met all of my anticipations and I am in the process of recomending its use on future sites.

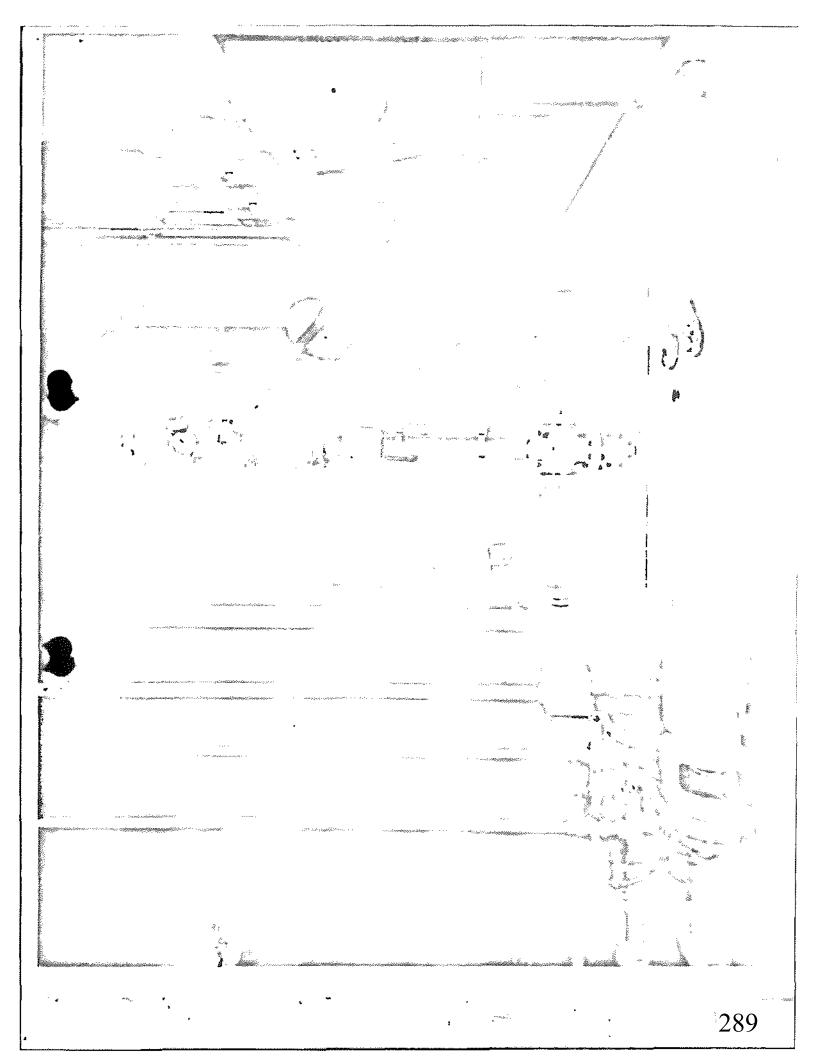
The plant was inspected by the state water board and met with its approval.

Respectfully.

William C. Homever

Piping Supt.

United Engineers & Constr.







PRODUCT DATA SUMMARY

TRANS- ACTION	DATE MM- YY 10-75	TOXICITY CODE 3	Y PRODUCT Code 33	MANAGER NAME J. BANKS	REGI STRATI ON NUMBER 035900-00002
		Mire Mire			
HYGENE					1
14, 24.12 m m 42 cm 1	TYPE CODE	ann ann ann aige Alle-Alle Air Air Air ann Ai	TYPE		and the state of t
	24	BACTERIO	STAT		
16-16-16-16-16-16-16-					
	FORM CODE		FORM		
	67	GR ANUL AF	R PELLETED O	R CRYSTAL PRODUC	T
	Hân Hân				
	CHEM	ひたりぐだいて	CHEMI	CAL	
	COOE 072501	PERCENT 1.0500	SILVER		
	484-4 87-488 -484-484-484-	नोकंत स्वयं-त्राह्म-स्वयं-पिकेंग वेतिन व्यक्त			l
					,





INSTRUCTIONS

NOTE: Use a separate form for each Formulation.

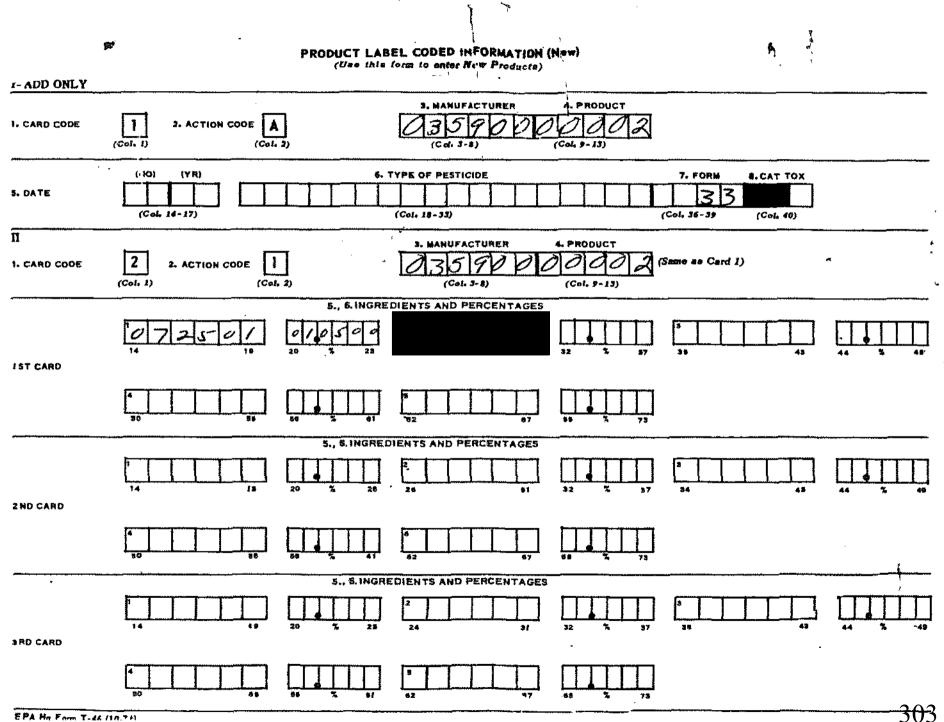
Applicant - keep the second copy for your files and forward the original to EPA or follow the interest in below

- A. The complete chemical composition of each pesticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide and Rodenticide Act. This information is also necessary to determine the status of ingredients, both active and inert, under the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act.
- B. This form is designed for reporting the ingredients used in the formulation of a pesticide. Its use will speed the review. It must be completed and submitted with each EPA Form 8570-1, Application For New Registration Of A Pesticide, or with each EPA Form 8570-2, Application For Amended Registration Of A Pesticide, if revision Involves a formula change, or with each EPA Form 8570-3, Application For Renewal Registration Of A Pesticide.
- C. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of these forms for each ingredient to your Basic Supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your pesticide. The Basic Supplier is then requested to complete items 1, and 9 thru 15, and submit the form to this Division. This statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ITEM No.

- 1. If more than 1 page is required, number them "1 of 2", "1 of 3", etc.
- 2. Enter the same date as the Application.
- 3. Read instruction "B" above.
- 4. Enter the name and address of your firm.
- 5. Enter the product name of this pesticide as it will appear on the finished label.
- 6. Enter the EPA Registration Number or File Symbol if known.
- 7. Complete if required by instructon "C" above.
- 8. Complete if required by instruction "C" above.
- 9. Completed only by Basic Supplier.
- 10. Completed only by Basic Supplier.
- 11. List first all active ingredients then the inert ingredients each in the exact order as they will appear on the finished label. When a formulated product is listed in the formula, name its basic manufacturer and give its EPA Registration No., if known, in parenthesis following the name of the product. (Also see instruction "C" above.) The trade name and manufacturer of surfactants and other adjuvants (dyes, emulsifiers, solvents, perfumes) must be listed. The complete chemical composition of emulsifiers and surfactants must be listed. Enclose the manufacturer's name in parenthesis following the product listed by trade name. (Also see instruction "C" above.) If a dye or other coloring is used, state the color.
- 12. Enter the percentage by weight of each active and inert ingredient beside the ingredient to which it applies. The percentages by weight for the active ingredients must agree with those appearing in the ingredient statement on the label. The sum of all percentages listed must equal 100 percent.
- 13. Self explanatory.
- 14. Self explanatory.
- 15. Self explanatory.

Proprietary inert ingredient coding may be entitled to confidential treatment PRODUCT LABEL CODED INFORMATION (New) (Use this form to enter New Products) 1- ADD ONLY 3. MANUFACTURER 4. PRODUCT 1. CARD CODE 2. ACTION CODE



Manufacturing process information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

February 19, 1976

Mr. James H. Banks, Product Manager (33)
Disinfectants Branch
Registration Division (WH-567)
United States Environmental Protection Agency
401 M Street S.W.
Washington, D. C. 20460

Subject: HYgene

EPÅ Reg. No. 35900-2

Your Letter of Jan. 20,1976

Dear Mr. Banks:

This is in reply to your letter dated January 20, 1976 in reference to general chemistry data for HYgene.

A.1 You are correct in stating that the active ingredient is essentially 100% metallic silver with only traces of impurities.

бK

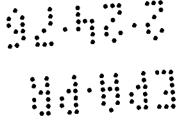
A.2 Correct. Manufacturing process is the same as in Petition 5H5079.

oK

A.3 Purity of ingredients used in the manufacturing process of HYgene are as follows:









				1.		REGISTR	ATION N	JMBER		CYCL	Œ 2.	04	TE:F	ECE	IV€D	> >
			REVIEW RECORD G		9	00	-		2		1	3	Ď	8	Ž,	3
3	. 3CIE	PUBLICA	ATION NECESSARY	4, PE7	TITION	I NO.					Б,		·		TEA	
		YES	X No									MD	D,	AY]	Y	PA
F	. MET	1100 OF S	SUPPORT	7. PR	руст	MANAC	EP	<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>		NO.	8.	PROJ	ECTE	OR	ETUF	AN.
		24 [28 [] 2C	1	Sa	nk	5			33		10	0.	AY	Y	n
10	OATE	PULLEO	10, OATE PUBLISHEO	11. AC	TION	TYPE			11	COO	E 12,	OUT	GOIN	G O	ATE	<u> </u>
	_			Ke	જવા	mas	SIÓN	withou	Odla	5/	/	Mo	0.	AY	Y	R
	. ⊯ ⊯			REVIE	WER					COM	D,	ATE P	EVIEV	W CO	MPLE	TEO
REV	A PEC	3	REVIEW TYPE	COC (Initi		SIG	NATURE	OF REVIE	WER	CODI		<i>4</i> 0	0,	LΥ	Υ	/ PR
	A	REVIEY	YABILITY TEAM									<u></u>				
	В	Ekkic v	CT MANAGER TEAM LCY REVIEW													
	С		CT MANAGER TEAM SAPETY REVIEW						· • · · · · · · · · · · · · · · · · · ·						1	
	D		ENTAL SAFETY REVIEW CT MAN AGER TEAM EN-									<u> </u>				
	E		CT MANAGER TEAM MISSION REVIEW	RE		R	Dou	Nas		SP	31	12	â	2	Z_1	5
L	F	PRDDU	CT MANAGER				<u> </u>		,						[
	G	INTERA	GENCY REFERRAL									<u></u>				
	Н	COST-B	EMERIT REVIEW												sia: .]	
	ı	PUBLIC	COMMENTS REVIEW													
	J	EEE BR	AHCH INSECTICIDE CY												× · ·	
	K	ERE BR EFFICA	ANCH HERBICIDE CY						,							
١,	L	E FFICA	ANCH FUNGICIOE CY			- 33			·•							
, `` ,	M	EFFICA	ANCH ROOENTICIOE CY				<u>.</u>	_				<u>L</u>				
	N	EEE BR EFFICA	ANCH DISINFECTANT CY	DW	P	0	. Fê	itne	~							
	0		TRY BRANCH E CHEMISTRY													
	P	EEE BR MENTAL	ANCH ENVIRON - CHEMISTRY													
	a		LOGY BRANCH SAFETY			demokratikanska samben						<u> </u>				
	R		AHCH ENVIRON- , SAFETY					<u></u>	····		<u> </u>					
L	S					,					<u> </u>					
	T			1	1								J		I	
PF	ODUC	TMANA	BER SIGNATURE		·		RESPON	·				J			ODE	
Y	7		H. Ban	1.		To	s G. 1						Ī	T		
L	Ken	uld	18. Can			مي الم	ブ・ ()	<u> </u>						}	·l	



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

October 14, 1975

AIRMAIL - SPECIAL DELIVERY - CERTIFIED MAIL - RETURN RECEIPT REQUESTED - ADDRESS ONLY

United States Environmental Protection Agency Disinfectants Branch, Room 321 Registration Division (WH-567) OPP - EPA 401 M. Street, S.N. Washington, D.C. 20640

Attention: Mr. James H. Banks - PM 33

Subject: HYGENE

Ionics File Symbol 35900-E

Your letter dated October 9, 1975

Dear Mr. Banks:

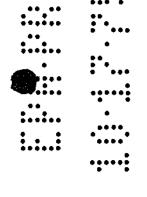
Five finished labels for the above HYgene product are enclosed. On this label, we have made the following changes as requested in your letter dated October 9, 1975:

- 1) We have changed "Self-sanitizing" to read "Bacteriostatic".
- 2) We have changed the claim "Prevent the growth of bacteria" to read "Inhibits the growth of bacteria".
- We have deleted "as a sanitizer".
- 4) We have corrected the typographical error in the spelling of silver.
- 5) In your letter under paragraph 5, you ask us to provide the necessary calculations to verify the flow rate recommended on the label is comparable to the flow rate used in these laboratory experimentation studies.

You may use the following equations to convert the 500 ml/minute and this will show that this is the same as 15 gallons per minute. The equation is as follows:

500 ml flow through column of 250 cc HYgene mineral is directly proportional to 15 gallons per minute per cubic foot of HYgene as follows:

- a) 500 ml/min. = 0.132 gal./min.
- b) 250 cc HYgene = 0.008828 cubic foot
- c) 0.132 gal./min./0.008828 cubic foot = 15 gals. per minute per one cubic foot.



United States Environmental Protection Agency

October 14, 1975

Attention: Mr. James H. Banks - PM 33

Page 2

6) We have no collateral literature or technical bulletins or brochures that are being distributed with this product at present.

We have enclosed a copy of a letter that is being sent to all of our customers. If any literature or collateral materal is developed to be sent with the product, we will send this to you for your approval.

In your letter dated October 9, 1975 under paragraph "D" 1, 2, 3, and 4 - you asked for additional information required to substantiate the bacterio-static claim for the filter media.

- 1) Attached please find a letter from Ms. Linda Deans, Manager of Analytical Services for NUS Corporation who did the testing. In this letter Ms. Deans gives the concentration of the artificially contaminated water (inoculum) at the end of the test to ascertain the degree of natural "dieoff".
- 2) The neutralizing solution used contained 5% sodium thioglycollate and 7.3% sodium thiosulfate. One milliliter of this sterile neutralizing solution was added to sterile sample bottles in which 100 milliliters samples were collected for bacteriological testing.
- 3) Attached is a copy of our report "EVALUATION OF HYGENE PRODUCT MEDIA FOR EPA REGISTRATION". This was originally sent to you on September 3, 1975. Please note on page one under CHEMICAL, there is a listing of the production lots used for testing. Three of these lots are as follows:

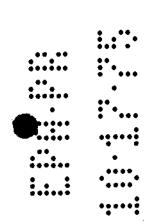
Lot No. 05125, Lot No. 04075, Lot No. 03105

On page three of this report under BACTERIOLOGICAL, we list the three lot numbers used for bacteriological testing.

Lot No. 05125, Lot No. 04075, Lot No. 03105

Please note that these are both from the same lot numbers that we used in the chemical testing.

I refer you to the last paragraph on page two which states "Flow was discontinued to all three columns for a period of eighteen (18) hours." These samples were then acidified and sent to NUS Corporation with the suffix "C" and tested by atomic absorption for silver concentration. This included lot numbers 05125, 04075, and 03105. They were identified then as lot numbers 05125C, 04075C, 03105C. Attached to the above reference report is the NUS Corporation Atomic Absorption Test Report on the silver by lot numbers. None of the three lots went over the 50 ppb after an eighteen hour holding period. This conclusively proves that from these lots even sitting eighteen hours, we did not exceed 50 ppb. These are the lots that we used for the bacteriological tests.



,	,			Record No	ımber <u>4342/</u>	
4					: Humber 2	
444 THE PROVE PRO	1001 15177046 (eno decisto	ATTON/AMENOMENTS	Inpu	t Date <u>7-2/-8</u>	
CODING FORM FOR	759/1	1-2	ATTON/AMENOMENTS [2] PM 3 / [3]	8	300	
[]] File SymbolyR	leg.No.		Z PM — / [3]	ACTION CODE <u>C</u>		
				• •		
S. Intrastate Ca	111-in // ()	f)Yes				
		()No	•		•	
7.Child-resista	nt Packaging:	8.Re	gistration Type:		•	
// (Y)Yes	(N)No	/_	/ (1)Condition	nal //(2	Unconditional	
9.Proposed Clas	sification:	10.F	inal Classificat	fon:		
/ (R) Re	stricted	ĺ.	/ (R)Restric	ted // (N)Not Classified	
(G) Ge	meral	Í,	/ (G)GeneraI			
Date on App1		EPA Recei	ved Date:	13 Date Rece	ived by PM.	
16/	a 81/	16/			1781	
. MO DA 20.Method of S	•••	KO	DAY YR 21.Certif	MQ ication State	DAY YR ⊇ment:	
		(4)Not Appl			(3)Not Applicable	<u>.</u>
	.		itted / (,		•
/ (3)Cos	/ `	(0)	ا بيکي (Fluor Armuser		
24 Reviews Requests	<u>-</u>		•			
	DATE	DUE	DATE.	RESPONSE	RESPONSE	
	SENT	DATE	RETURNED	CODE	DATE	
100 - <u>80</u>						
. PH	1.5			12	6-26-81	
FL.						
CH						
EF		·				
26 Status:					•	
12013 44 443.					· · · · · · · · · · · · · · · · · · ·	
27 FINAL R	lesponse	Respo	nea l	1	· ·	
	code /2	Date	07/		•	
[9°C] *** ***	ANALISE BUT BETT			AY YR	310	
LCOL /D-UAY RE	SPONSE DUE DATE	: //(Y)	Yes / /(N)No) <u> </u>		

Office of Enforce	ides Enforcement Division	1.D. NO.
Office of Enforce		172045
	ement and General Counsel	EPA REGISTRATION NO.
ODUCT NAME (On #AM	pie label)	
BOH-DEL BAC	TERIOSIATIC WATER UNIT	
MPANY NAME AND AC	ODRESS (On sample label) (Include ZIP code)	REGISTRATION STATUS AT TIME DF
Bon Del Inc	•	REGISTERED
157 S. Pome Messa, AZ 85		NOT REGISTERED
	DISTRIBUTOR STATUS AT TIME D	F SHIPMENT (II applicable)
IC PRODUCT NAME		PRODUCT SUPPLEMENTALLY REGISTERED
_		YES NO
TRANT NAME AND	ADDRESS (Include ZIP code)	DATE OF SUPPLEMENTAL REGISTRATION
•		
1		average and the second
ridgeville, Bon Del Inc. registered u They have th	clostatic Water Filter Media" will MATER UNIT is registered to PA. 15017 for product name HYD., Mesa, AZ 85202 (company number Mesa, Reg. No. 35900-2. The ree applications pending (1) A3	IDNICS, Inc., P.O. Box 99, ENE under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products.
*The *Bacter BACTERIOSTAT Fridgeville, Bon Del Inc. registered u They have th 43430-E for	ciostatic Water Filter Media" wi FIC WATER UNIT is registered to PA. 15017 for product name HYO , Mesa, AZ 85202 (company number mider EPA Reg. No. 35900-2. The	IDNICS, Inc., P.O. Box 99, ENE under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products.
The *Bacter BACTERIOSTAT Tidyeville, Bon Del Inc. registered u They have th 43430-E for applications	ciostatic Water Filter Media" with the Water Unit is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number Mesa, Reg. No. 35900-2. The ree applications pending (1) 43 BON DEL MODEL TRO. (3) 43430-G dated 10-16-79).	IONICS, Inc., P.O. Box 99, EMS under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for applications HIS A PESTICIDE?	ciostatic Water Filter Media with the Water Unit is registered to PA. 15017 for product name HYO., Messa, AZ 85202 (company number Messa, AZ 85202 (company number EPA Reg. No. 35900-2. The pres applications pending (1) 43 BON DEL MODEL TRI, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for applications HIS A PESTICIDE?	ciostatic Water Filter Media with the Water Unit is registered to PA. 15017 for product name HYO., Messa, AZ 85202 (company number Messa, AZ 85202 (company number EPA Reg. No. 35900-2. The pres applications pending (1) 43 BON DEL MODEL TRI, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for applications HIS A PESTICIDE?	ciostatic Water Filter Media with the Water Unit is registered to PA. 15017 for product name HYO., Messa, AZ 85202 (company number Messa, AZ 85202 (company number EPA Reg. No. 35900-2. The pres applications pending (1) 43 BON DEL MODEL TRI, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. or 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water Unit is registered to PA. 15017 for product name HYO., Messa, AZ 85202 (company number Messa, AZ 85202 (company number EPA Reg. No. 35900-2. The pres applications pending (1) 43 BON DEL MODEL TRI, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for suplications HIS A PESTICIDE? TICIDE CLAIMS	ciostatic Water Filter Media with the Water UNIT is registered to PA. 15017 for product name HYO., Mesa, AZ 85202 (company number EPA Reg. No. 35900-2. The tree applications pending (1) 43 BON DEL MODEL TRIE, (3) 43430-G dated 10-16-79).	IONICS, Inc., F.O. Box 99, ENE under EPA Reg. No. 35900-2. Tr 43430) is not supplementally by have no registered products. 1430-R for BON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all
The Becter BACTERIOSTAI Tridgeville, Bon Del Inc. registered u They have th 43430-E for applications HIS A PESTICIDE?	ciostatic Water Filter Media with the Water Unit is registered to PA. 15017 for product name HYO., Messa, AZ 85202 (company number Messa, AZ 85202 (company number EPA Reg. No. 35900-2. The pres applications pending (1) 43 BON DEL MODEL TRI, (3) 43430-G dated 10-16-79).	IONICS, Inc., P.O. Box 99, EME under EPA Reg. No. 35900-2, or 43430) is not supplementally by have no registered products. 1430-R for PON DEL MODEL R-1, (2) for BON DEL MODEL CT-5 (all



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

October 8, 1975

CERTIFIED MAIL - RETURN RECEIPT REQUESTED DELIVER TO ADDRESSEE ONLY

Mr. E. F. Brown Chief, Disinfectants Branch Registration Division (WH-567) United States Environmental Protection Agency 401 M Street S.W. Washington, D. C. 20460

SUBJECT: HYGENE - Ionics File Symbol 35900-E Ionics EPA Registration No. 35900-2

Dear Mr. Brown:

This letter will confirm our telephone conversation of Friday, October 3, 1975. From this phone conversation it is my understanding that the United States Environmental Protection Agency will issue to Ionics, Incorporated on their product Hygene EPA Registration No. 359DO-2. This number will be issued as soon as you receive the enclosed (5) labels that have the following revisions from the original label sent to Mr. James H. 8anks on September 3, 1975.

The revisions on the labels are as follows:

- We have changed the word "Self-sanitizing" to "Bacteriostatic".
- 2. We have changed the claim "Prevents the growth of bacteria" to "Inhibits the growth of bacteria".
- 3. We have deleted "As a sanitizer".
- 4. We are providing the following necessary calculations to verify that the flow rate of 15 gpm/cu.ft. recommended on the label is comparable to the flow rate used in our laboratory experimentation studies. In these studies we used 500 ml./min. flow through a column of 250 cc of Hygene mineral. This is directly proportional to 15 gpm/cu.ft. of Hygene as follows:
 - a. 500 ml./mln. = 0.132 gpm
 - b. 250 cc HYgene = 0.008828 cu.ft.

c. 0.132 gal./min./0.008828 cu.ft. = 15 gal./min./cu.ft by direct proportion.

PEGISTRATION DIVISION

Mr. E. F. Brown Chief, Disinfectants Branch Registration Division (WH-567) United States Environmental Protection Agency October 8, 1975 Page 2

It is our understanding that we are to provide you with copies of any collateral literature such as technical bulletins and brochures distributed in connection with this product for your review. At the present we have no literature that will be sent with the product. We are enclosing a copy of a letter we are sending to some of our potential customers.

I would like to take this opportunity to thank you and all of your staff for the cooperation we received.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosures

cc: Mr. James H. Banks





P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

Water Conditioning Equipment . Custom Fabrication for the Muclear, Chemical & Food Industries . Heat Transfer Equipment

This letter is to inform you that Ionics, Incorporated has been granted its Federal Registration Number from the Environmental Protection Agency for its product Hygene.

HYgene has been registered under the Federal Insecticide/Fungicide/Rodentcide Act and has received a Bacteriostatic rating. The Federal Government allows us to make the following claim - that our product will inhibit the growth of bacteria.

We can now honor all purchase orders and make immediate shipment of this product.

We are enclosing our current O.E.M. price list.

May we look forward to hearing from you with your requirements.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

Walter J. Polens Vice President

WJP:mle

Enclosure



Tonics, Incorporated P.O. Box 99 Routes 519 & 50 Bridgeville, PA 15077

17 JUL 1881

Attention: Welter Polens

Gentlemen:

Subject: Bygene Becteriostatic Water Filter Media RPA Registration No.: 35900-2 Amendment Application Date: June 12, 1981

A preliminary review of the subject application has been made. However, before the amendment can be processed further, clarification is needed in the following regard.

- (a) Please explain if 1.05% as declared on the label is that of "Silver" or is it "Silver nitrate Your label accepted October 29, 1975 declared "Metallic silver - 1.05%."
- (b) Is it the same product? Please clarify.
- (c) If your label declares "silver" from "silver nitrate" than you may declare no more than 0.67%. Explain why you wish to change your formulation?

Sincerely,

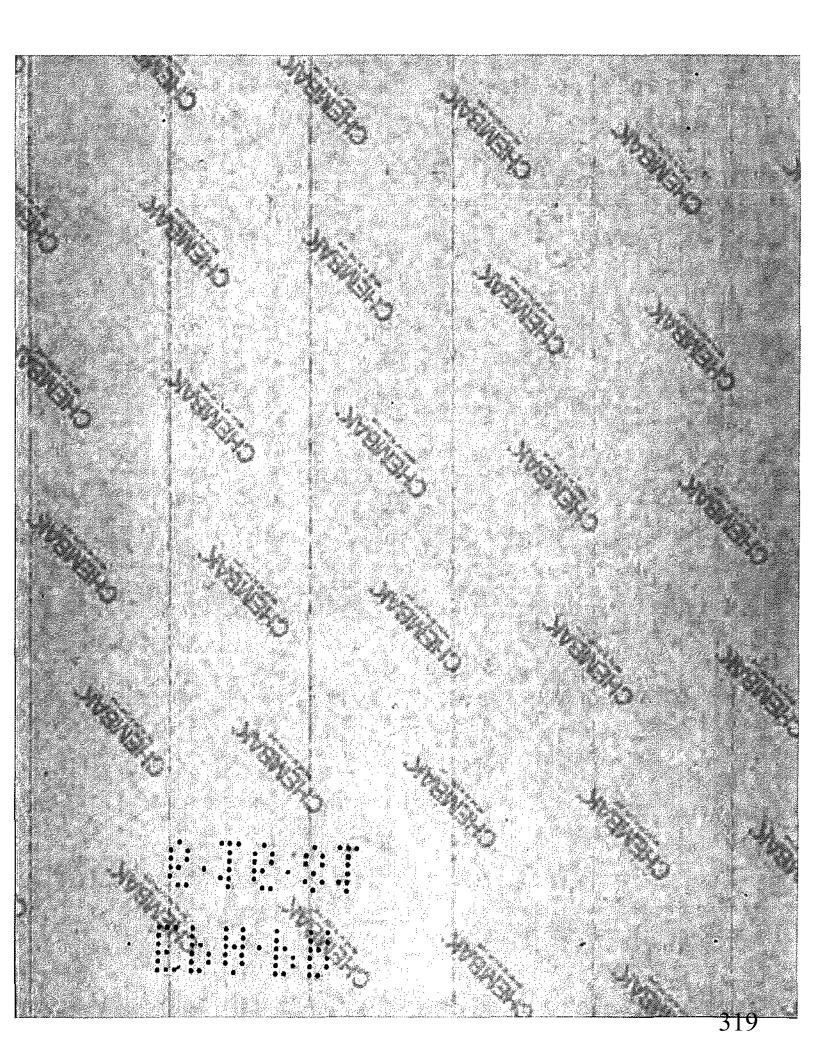
John H. Lee
Product Hangger (31)
Disinfectants Brench
Registration Division (TE-767C)

EPA:TS-767C:JHLEE:46073:1725A:479-2018:7/6/81

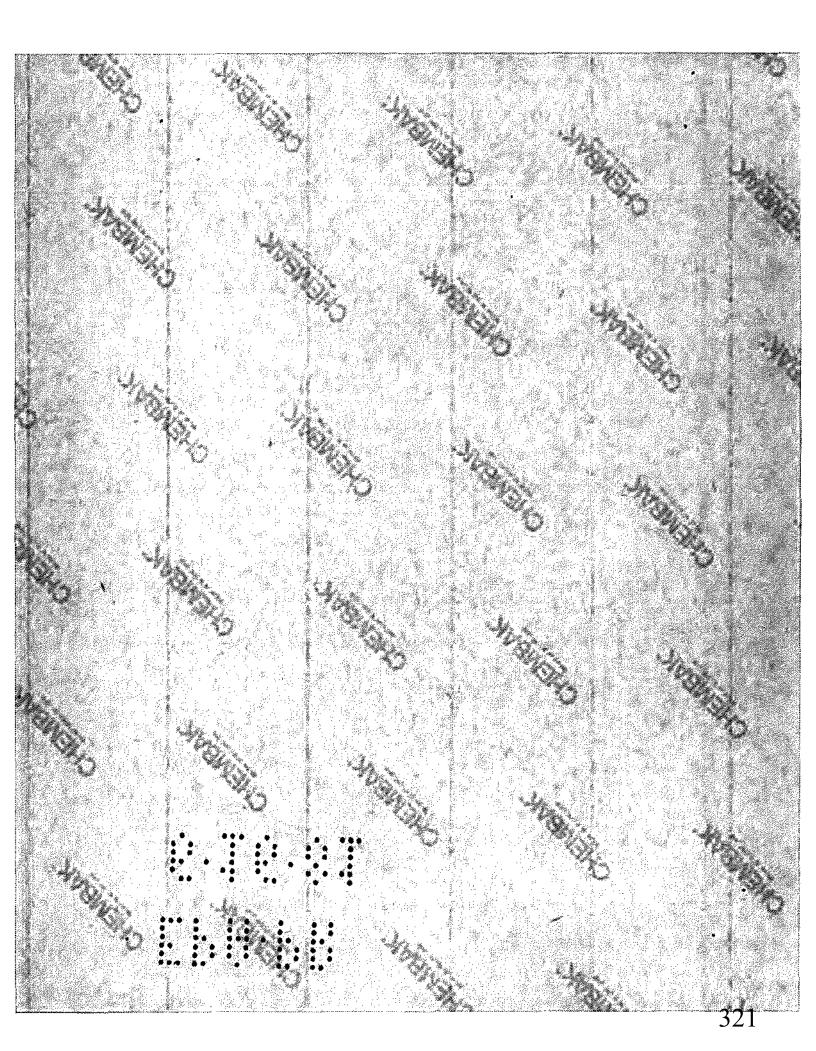
	•••
Removes objectionable tastes, odors, color from treated municipally— supplied tap water.	
Inhibits the growth of bacteria within the filter .::: media bed.	•
CAUTION: KEEP OUT OF REACH OF CHILDREN	::
EPA Reg. No. 35900 - 2 EPA Est. No. 35900 PAOJ.	••
ACTIVE INGREDIENT SILVER as Ag NO ₃ 1.05 % LOT No	
INERT INGREDIENT ACTIVATED CARBON98.95 % NET CONTENTScu.ft.	
STORAGE Store in closed container which excludes moisture and fumes.	
DIRECTIONS FOR USE————Refer to enclosed product data sheet.	
DISPOSAL OF SPENT MEDIA Retain Shipping carton and liner for disposing of exhausted filter media with trash.	
USE This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.	
Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.	
IONICS, INC. Routes 519 & 50 P.O.Box 99 Bridgeville, Pa. 15017	4



BACTERIOSTATIC WATER FILTER MEDIA ::::
Removes objectionable tastes, odors, color from treated municipally—supplied tap water. Inhibits the growth of bacteria within the filter media bed.
CAUTION: KEEP OUT OF REACH OF CHILDREN :::
EPA Reg. No. 35900 - 2 EPA Est. No. 35900 PA OI
ACTIVE INGREDIENT SILVER as Ag NO ₃ 1.05 % LOT No
INERT INGREDIENT ACTIVATED CARBON98.95 % NET CONTENTScu.ft.
STORAGE Store In closed container which excludes moisture and fumes.
DIRECTIONS FOR USE————Refer to enclosed product data sheet.
DISPOSAL OF SPENT MEDIA Retain Shipping corton and liner for disposing of exhausted filter media with trash.
USE This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.
nother fine product by the manufacturers of General lonics Water Conditioning Equipment.
IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017



BACTERIOSTATIC WATER FILTER MEDIA.::::
Removes objectionable tastes, odors, color from treated municipally—supplied tap water.
Inhibits the growth of bacteria within the filter ·::::::::::::::::::::::::::::::::::::
CAUTION: KEEP OUT OF REACH OF CHILDREN :::
EPA Reg. No. 35900 — 2 EPA Est. No. 35900 FA01
ACTIVE INGREDIENT SILVER as Ag NO ₃ 1.05 % LOT No
INERT INGREDIENT ACTIVATED CARBON98.95 % NET CONTENTScu.ft.
STORAGE Store in closed container which excludes moisture and fumes.
DIRECTIONS FOR USE———— Refer to enclosed product data sheet.
DISPOSAL OF SPENT MEDIA Retain Shipping carton and liner for disposing of exhausted filter media with trash.
USE This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.
nother fine product by the manufacturers of General Ionics Water Conditioning Equipment.
IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017



BACTERIOSTATIC WATER FILTER MEDIA Removes objectionable tastes, odors, color from treated municipally— supplied tap water. Inhibits the growth of bacteria within the filter media bed. CAUTION: KEEP OUT OF REACH OF CHILDREN EPA Reg. No. 35900 - 2 EPA Est. No. 35900 ACTIVE INGREDIENT SILVER as Ag NO₃ ---- 1.05 % LOT No._____ INERT INGREDIENT ACTIVATED CARBON---98.95 % NET CONTENTS_____cu.ft. STORAGE ---- Store in closed container which excludes moisture and fumes. DIRECTIONS FOR USE---- Refer to enclosed product data sheet. DISPOSAL OF SPENT MEDIA --- Retain Shipping carton and liner for disposing of exhausted filter media with trash. USE---- This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017



BACTERIOSTATIC WATER FILTER MEDIA

Removes objectionable tastes, odors, color from treated municipally—supplied tap water.
Inhibits the growth of bacteria within the filter media bed.

CAUTION: KEEP OUT OF REACH OF CHILDREN EPA Reg. No. 35900 - 2 EPA Est. No. 35900

ACTIVE INGREDIENT

SILVER as Ag NO₃ ---- 1.05 % LOT No.______

INERT INGREDIENT

STORAGE ---- Store In closed container which excludes moisture and fumes.

DIRECTIONS FOR USE---- Refer to enclosed product data sheet.

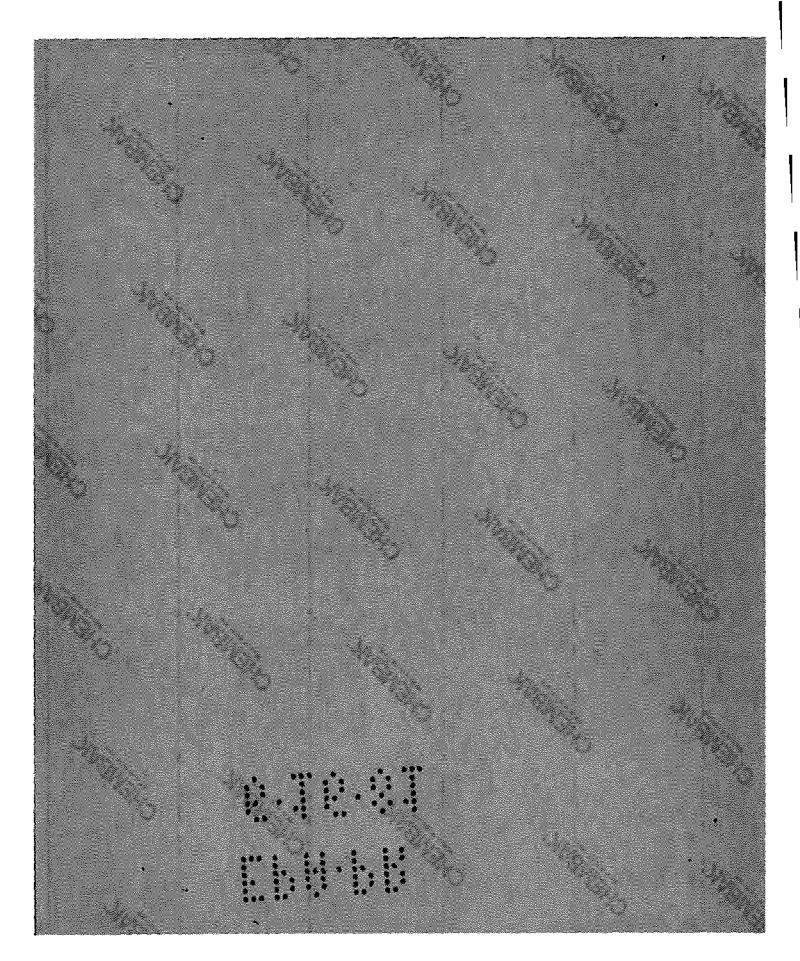
DISPOSAL OF SPENT MEDIA--- Retain Shipping carton and liner for disposing of exhausted filter media with trash.

ACTIVATED CARBON---98.95 % NET CONTENTS_____cu.ft.

USE----- This product is to be used only for manufacturing or fabricating Bacteriostatic Water Filter Products for home use.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment.

IONICS, INC. Routes 519 & 50 P.O. Box 99 Bridgeville, Pa. 15017



ENFO	RCEMENT CASE R (Test and Label)		ID HUMBER EC-79-28 EPA REGISTRATION NUMBER 3 5 9 00 - 2 PE OF REVIEW				
	1 1	T T	OTHER (Specify	·)			
CHEMISTRY	EFFICACY	SAFETY					
No	anch, so	is perfe	ned				
X Y EE (II yoo,	NIFICANT LABELING (Ifot essbetantial discrept EPANCIES AND SIGNIF	DEFECTS? Profee and elgolitoano	LING REVIEW	No	DATE OF ACCEPTANCE OF APPLICABLE LABELING		
Sec	. D.111.	Portne	r's reve				
e soor"				weller 31-79			

		O NUMBER	
ÉNFORÇEMENT CASE REVIE	:w [EC -79-26 EPA REGISTRATION HUMBER	······
(Test and Label)	Ì	•	
	TYPE OF	REVIEW	
CHEMISTRY N TERICACY	SAPETY	OTHER (Specily)	
CHEMISTRY X EFFICACY			
The following claims or	n the Robe	ling are considers	d under the
provisiones inducated	m Sactio	~ 162110 (0) (5) 070	e nomena
for Enforcement of FIF	RAOSFO	lax and mosterday	biopin
1. The posticidal las	me for d	Timpesting water	wer improgneted
100% buters exceed	en me	orporated in this wal	a tractment device
2. The mon-pasticules	(James	for nemoved of 120	saticides such
as I Chlorobona . 9. Toke	appeared	ingrestral	
and a lacatorismore	_ 11.7.31	which was a former and	
morganics found in a the voice of this water	rter one	eas 2, Cersonie!	
the voice of the unti	in fellar m	war for puck for	· / · · ·
	4		# 1747
3. The Juin "The most	uttions	, walnut and purpor	money of the mine
	LABELIN	GREVIEW Ind person	
ARE THERE ANY SIGNIFICANT LABELING DEFE	LABELIN CTS?	G REVIEW	DATE OF ACCEPTANCE OF
	LABELIN CTS?	G REVIEW	
ARE THERE ANY SIGNIFICANT LABELING OFFEC	LABELIM CTS? and algnittcances b	elow) No	DATE OF ACCEPTANCE OF APPLICABLE LABELING
ARE THERE ANY SIGNIFICANT LABELING DEFECTION TES (It yes, that substantial discrepancies substantial discrepancies and significance approved by 12, 14, 15, 14, 15, 16, 17, 18, 18, 18, 18, 18, 18, 18, 18, 18, 18	LABELING CTS? and eigniticances b ES Church	elow) No	DATE OF ACCEPTANCE OF APPLICABLE LABELING (EPA #
ARE THERE ANY SIGNIFICANT LABELING OFFER TES (If you, flat substantial discrepancies SUBSTANTIAL DISCREPANCIES AND SIGNIFICANC SYMPTOTE OF TEXTS 4 Unline your town	LABELING CTS? and eigniticances b CES 2 2 1 Howaii	eson or indured by	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE EPH. Compare EPH. Compare English Compare
ARE THERE ANY SIGNIFICANT LABELING OFFER TES (If you, flat substantial discrepancies SUBSTANTIAL DISCREPANCIES AND SIGNIFICANC AS 400-2) implies and 4 Underly from the	LABELING CTST and algniticances b ESS Churion Al Howard Labeling	eson No	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE PH. Le EPH. Choenix Eagles Lagranged
ARE THERE ANY SIGNIFICANT LABELING DEFECTION TES (It yes, that substantial discrepancies substantial discrepancies and significance of the substantial discrepancies are the substantial discrepancies are the substantial of	LABELING CTST and eigniticances b ES Enveron Il Howard The new Ymanfo	eron or indured by Empera, or spepara, which we have the service of the service o	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE EPH. Loenie Reg Teg Loenie Reg Teg Loenie Reg Teg Loenie Reg Teg Loenie Reg Teg Loenie Reg Teg
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (It yes, that substantial discrepancies substantial discrepancies of the substantial discrepancies and significance of the substantial from the substantial of the substantial labeling, to the purchoses the substantial the substantial of the substantial the substantial of the substantial the substantial of the substantial the substantial of the su	LABELING CTST and eigniticances b ES Enveron I Howard The san	esons No mantal Protection of them or indured appears, Empers, Organs	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE EPH. Companyed Le sife Twe water,
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (It you, that substantial discrepancies substantial discrepancies and significance of the substantial from the substantial from the substantial for the purchase had a substantial to the purchase the substantial to the purchase the substantial to the purchase the substantial to the purchase the substantial to the purchase the substantial to the purchase the substantial to the purchase the substantial to the substantial t	LABELING CTST and algoriticances b ES Environ Al House The sen alleten	eson No No The or indured by Engine, Empera, which we prepared which we ple product will be from Industry E pp Progratulion	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE EPA. Companyed Le sife two water, mumber for
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (IT you, that substantial discrepancies SUBSTANTIAL DISCREPANCIES AND SIGNIFICANC SSYDU-2) - myshis was H british from the man of the sample labeling, to the purchase had un eliminating the 1 5. The sample labeled to the worter of the makes	LABELING CTST and algalitosances b ES Enveron I House The sem Sulletan Was in 2	eson ho mantal Protection of turn or indurer Enging, Empera, of Enging, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, empera, em	DATE OF ACCEPTANCE OF APPLICABLE LABELING PLOS EPH. Companyed Je sife Twe water, much for EPA Rysatrotion
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (It yes, that substantial discrepancies substantial discrepancies of the substantial discrepancies and significance of the substantial from the substantial of the substantial labeling, to the purchoses the substantial the substantial of the substantial the substantial of the substantial the substantial of the substantial the substantial of the su	LABELING CTST and algalitosances b ES Enveron I House The sem Sulletan Was in 2	eson ho mantal Protection of turn or indurer Enging, Empera, of Enging, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, empera, em	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE PA + Locale Labelino Le Sept. Le sife Twe water, much for EPA Rysatrotion
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (IT you, that substantial discrepancies SUBSTANTIAL DISCREPANCIES AND SIGNIFICANC SSYDU-2) - myshis was H british from the man of the sample labeling, to the purchase had un eliminating the 1 5. The sample labeled to the worter of the makes	LABELING CTST and algalitosances b ES Enveron I House The sem Sulletan Was in 2	eson ho mantal Protection of turn or indurer Enging, Empera, of Enging, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, empera, em	DATE OF ACCEPTANCE OF APPLICABLE LABELING PLOS EPH. Companyed Je sife Twe water, much for EPA Rysatrotion
ARE THERE ANY SIGNIFICANT LABELING DEFER TES (IT you, that substantial discrepancies SUBSTANTIAL DISCREPANCIES AND SIGNIFICANC SSYDU-2) - myshis was H british from the man of the sample labeling, to the purchase had un eliminating the 1 5. The sample labeled to the worter of the makes	LABELING CTST and algalitosances b ES Enveron I House The sem Sulletan Was in 2	eson ho mantal Protection of turn or indurer Enging, Empera, of Enging, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, Empera, of Engine, empera, em	DATE OF ACCEPTANCE OF APPLICABLE LABELING LE EPA. Loenix Tay Tay Le effetive Le

Product ingredient source information may be entitled to confidential treatment



P. O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017 PHONE A. C. 412 343-1040 TWX 5106973299

January 13, 1977

Mr. E. F. Brown Chief, Oisinfectants Branch Registration Division (WH-567) U. S. Environmental Protection Agency 401 M Street S. W. Washington, D. C. 20460

Dear Mr. Brown:

This letter will authorize you to use any information that is in Ionics, Incorporated's file, our EPA Registration 35900-2, to support registration of additional products for

This letter does not, however, allow you to make public to or anyone else any information in our file that would be considered proprietary information or confidential.

We thank you very much for your cooperation in this matter.

Very truly yours,

IONICS, INCORPORATED Bridgeville Plant

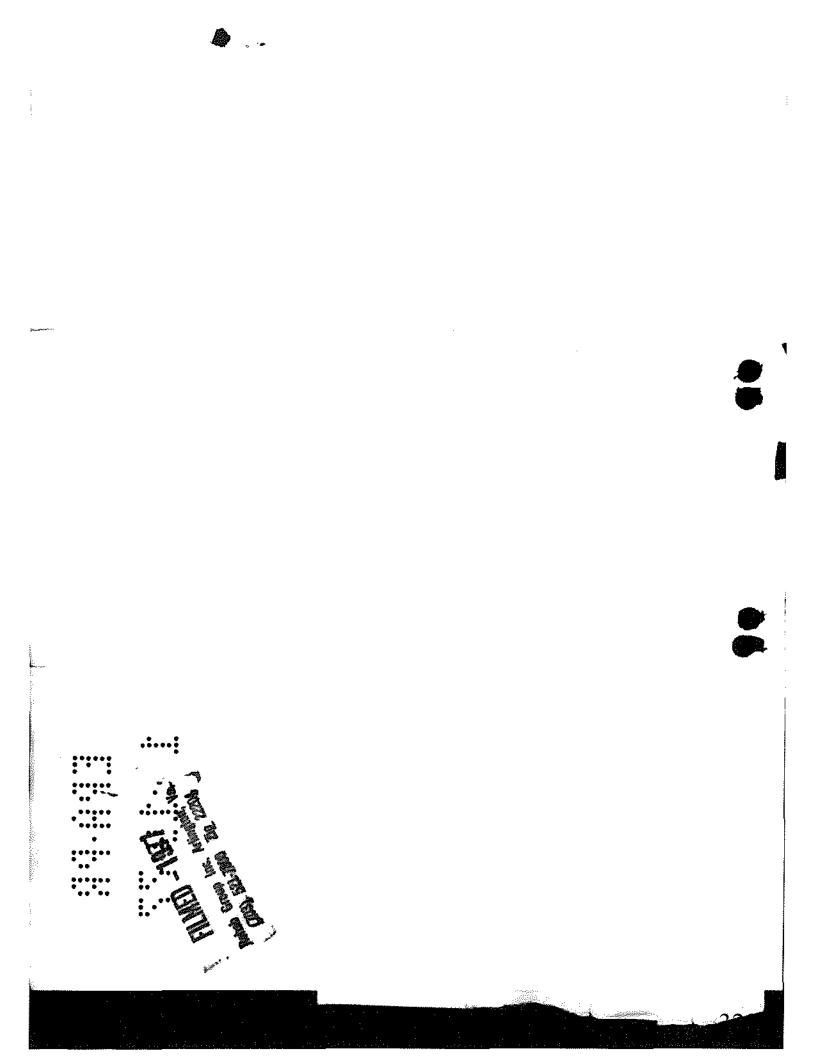
Walter J. Polens Vice President

WJP:mle

James H. Banks - EPA

J. D. Collins - Ionics

PM 33 Please place in EPA Reg No. 35900-2



DEC \$7 BIG

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Dear Mr. Polens:

This is to asknowledge receipt of your letter of June 22, 1976 regarding the Volkard Method of Amelysis. Assording to your letter it is our understanding that the Atomic Absorption Method of Analysis is being used by you or your agent(s) to analyse the "Hygens Bacteriostatic Water Filter Media" for silver content rather than the Volkard Method of Analysis. If our understanding of this matter is incorrect, please correct us.

Sincerely,

James H. Banks Product Manager 33 Disinfectants Branch Registration Division (WH-567)

WH-567:DIS:ROD:md:59040:Rm 321

12/17/76

REGISTRATION DIVIS ION

"M 07 ALB

IONICS. INC. Attn: Walter J. Polens P.O. Box 99 Bridgeville, PA 15017

Gentlemen:

Subject : LETTER OF May 11, 1976

The information submitted with your letter of May 11, 1976 regarding the Atomic Abserption Nethod of Analysis is acceptable. However, in order to satisfy the general chemistry data requirements, you must submit datails of the Volkard Method of Analysis as also requested in our letter of April 28, 1976.

Sincerely,

James H. Banks Product Manager 33 Disinfectants Branch (WH-567)

WI-667: DIS : RED: md: 59040: Rm 321 6/28/76

				1.			REGISTRATION NU	JMBER		CYCLE	2,	0/	ATE I	RECE	IVE	5
	SI	UB!	MISSION REVIEW RECORD	3	5	9	00-		2		/	13	7	ĵ	ブ	16
Γ	3, 3	CID	PUBLICATION NECESSARY	4.	PET	ITIO	N NO.				5,	REC	EIVE	D PM	TE/	\M
Ŀ	(<u> </u>	YES NO				*.				0	15	•	AY	٧	/FR
Γ	6. M	ETH	HOO OF SUPPORT	7.	PRO	DOUC	MANAGER			NO.	8,	PROJ	ECT	EO R	ETU	AN
L	[]	28		ý	<u> </u>	ints			33	0	ON	ĵ	<u>د</u> د	~}j	" (
- []	9, OA	∖T€	PULLED 10 OATE PUBLISHED	11.	AC.	TION	TYPE /		11	COOE	12.	OUT	4IOD	IG D	4TE	
					$ \underline{C} $	25	ubmissio	'nΞ	dala	52	J	N) 1°	Ŏ7		/R
Į	O C	YPE ODE	REVIEW TYPE		VIE	WER	SIGNATURE	OF REVI	EWER	COM- MENT	D/	ATE R	EVIE	w co	#LE	TEO
, and	SED.	⊁0 +0	***************************************		nisia		<u></u>			CODE	, h	#Ö	D	AY	¥	/R
	X	A	MAST YTIJIBAWSIV28	1	4	7	MAha	~yl~	<u>`</u>	MAC	0	<u>u</u> _	2	6	2	6
1		В	PRODUCT MANAGER TEAM EFFICACY REVIEW				0	0	/			L				
		С	PRODUCT MARKSER TEAM HUMAN SAPETY REVIEW			1										
		D	PRODUCT MANAGER TEAM EN- VIRONMENTAL SAPETY REVIEW													
		E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	1	,	10	R. Do	ma/a	is	PL	0	15	2	8	21	6
ſ		F	PRODUCT MANAGER	<u> </u>	,			<i>—</i>		:						
ſ		G	INTERAGENCY REFERRAL			1										1
Ī		Н	COST-SENEFIT REYIEW			1										
		ı	PUBLIC COMMENTS REVIEW	 	*******	<u> </u>						<u> </u>			 	
	1	J	EEE BRANCH INSECTICIDE EFFICACY	<u>+</u>]						<u></u>			ئـــــــ ا	
		ĸ	EEE BRANCH HERBICIDE EFFICACY	 				······································	······································				l		<u>_</u>	
		L,	EEE BRANCH FUNGICIOE EFFICACY	 											<u>.</u>	
ſ		М	EEE BRANCH RODENTICIDE EFFICACY			<u> </u>									 	
		N	EEE BRANCH OIMNPECTANT EFFICACY													
		0	CHEMISTRY BRANCH RESIOUE CHEMISTRY					•								
		P	EEE BRÂNCH ENVIRON • MENTAL CHEMISTRY													
		Q	TOXICOLOGY BRANCH NUMAN SAFETY													
		R	EEE BRANCH ENVIRON- MENTAL SAFETY	 						1			1		<u> </u>	:
ľ		s		 				······································					1 1		<u> </u>	
		7						······	······································							15 15
₽	noe	uc1	MANAGER SIGNATURE		^		TYPE OF RESPONS	BE AL						G	OOE	
X	1	1	ue H. Lan		7		Cag -	UG	•				Į.	1	X	//
Y _	f d	مهيد		FL.	<u> </u>			······································						1	<u>4</u>	7
57	7A F	9 7 (7)	6570-13 (3-75)				-							_	20	

4m. 7	OATE RECEIVED	REGISTRATION NO.	112876
SAMPLE SUMMARY ANALYTICAL REPORT	4/21/76 PRODUCT	35900-2	1128/6
ANALTICAL REPORT	1.0000		
	Hygene Bac	teriostatic Wat	er Filter Media
ALED			
Seal broken by Dallas Wright	., Jr.		
NTIFIED			
"SN 112876 03-23-76 ALDP	Sub 1"		LABELING SUBMITTED
Dallas Wright, Jr. by hand		ken	
SCRIPTION OF SAMPLE	DIC	wen	<u></u>
Plastic bag containing broke	n seal and one 7	oz. plastic bo	ttle with label.
Code "Lot No. 03226 B"		•	
PEARANCE			
Black granular solid; no odo	AMOUNT		<u> </u>
ANALYSIS	CLAIMEO	SATISFACTORY	UNSATISFACTORY
······			
	····		
	<u> </u>		
,			
Method: Silver extracted fr			
3 hours and standing solution added to a			
with silver nitrate			
lated as metallic s	-	,	
Results: 1 - 2.06%			
2 - 1.72% 3 - 1.91%			
		_	
average - 1.90% sil	ver (as metallic	c) Clair	a 1.05% metallic
•			silver
,			
			I
NATURE OF ANALYST	462		OATE REPORTED
Jack B. Looker	462		4/27/76
Jack B. Looker serve sample As rec'dsealed		ale D. Tank	i
Jack B. Looker ISERVE SAMPLE AS Tec'd SEALED 1.688 30-35 grams "11287 GNATURE OF SUPERVISOR () H. 6	6 4-27-76 Ja	ck B. Looker"	i



UNITED STATES **ENVIRONMENTAL PROTECTION AGENCY** WASHINGTON, D.C. 20460

REPORT OF ANALYSIS

Silver (Metallic) 1.05% Activated Carbon 98.95%

3. REGION

TTT

TED

4.201

24 hrs

						75 75 AS		
		SAMPLE IDE	NTIFICA"	TION				
4. LOT OR CODE NOIS).	032268		5. EPA REGISTRATION NO. 6. ESTABLISHMENT NO. 35900-24-01					
7. PRODUCT NAME	HYCKHE Bacterio	etatic Water	Filte	r Nedis"				
8. PHODUCER NAME AN IONICS, INC. Routes 519 and Bridgsville, I	4 50	P codej	9. DEAL	ER NAME AND ADDI	7E8S ,	'include ZIP codej		
	EMULS, CONC.	Press. SPRA	Υ	DUST	X	GRANULAR		
10.PHYSICAL FORM	WET. POWDER	AEROSOL		BAIT		ОТНЕЯ		
11, INGREDIENTS		-						

TEST 12. TYPE OF TEST 13. TEST ORGANISM(S) 14. METHOD NO. 15. DURATION E. coli Agar Cup 16. CONCENTRATION Staph. gureus Pseudomenas Eluorescens 17. DILUENT

18. SUMMARY

Sample was found to possess bacteriostatic activity against Escherichia celi, Staph aureus and Pseudomonas fluorescens.

19. RESULTS

Zomes of inhibition against: Escherichia celi Staphylococcus aureus Pseudomonas fluorescens

20, TESTER'SANITS. 21. SIGNATURE OF LAB SUPERVISOR 22. LABORATORY 23. DATE · (_ " Stul while

REPUBLICATION DIVISION

IONICS. INCORPORATED Attri. Harlier Polins P.G. BOX 19 Bridgaville, PA 15017 LOR 8 WIG

Continuen:

Subject to Machine

EPA Reg. No. 35900-2 Lean Testers of February 16, 19, 1976 and March 1, 1976

The general chartetry data is acceptable with the exception of A.5 and B.4. You should subsit details of the examic absorption and the Yolksen Methods of Analysis.

In regards to your suggested procedure for evaluation of Hygene Model Mr. 2 cartridge type filter for EPA Registration. Data derived in accordance with the test protocol submisted would meet the pacteriostatic officery data requirements indicated in our letter of December 24, 1975 for a grit witch processed puricipally treated tap water at a flow rate of 3 apartor at 18,750-gailon volume capacity. The acceptance of the left for the efficacy oldined is contingent upon the subsequent evaluation of the data developed in concurrence with labeling claims.

A copy of our recently preserved document "Interin Requirements for Registering Sectoriostatic Veter Freeteent Units for Home Dee' is enclosed to inform you of the test protocol to be used in testing future water typestment units that you develop. At this interin interval, you have the option of developing data by either the test protocol that you subditted or by the one indicated in the document enclosed.

Your submission of Desarber 5, 1975, in reference to Peel Rome, File Symbol 35900-R, is still under review. Due to the nature of the points related and/or objections stated in your letter in reference to our previous evaluation of your application, it was decared necessary that each of the five scientific

judgment. Three such evaluations have been made. However, two more are still required. As soon as in have received a resource from all of the disciplines involved, the information will be transmissed to you. We expect this review to be completed in approximately two weeks.

Sincerely,

James H. Banks Product Manager 33 Disinfectants Branch (MI-567)

Enclosure

H-667:015:000:ed:50040:0a 32) 4/23

Manufacturing process information may be entitled to confidential treatment

Jan 2 0 1076

Ionics, Incorporated Attn: Walter Polent P.O. Box 99 Bridgerille, PA 18017

Dear Stra

Subjects livgens
EPA Refs. No. 35000-2

We will accept your general chamistry data for MYGENE modia and all products using your modia if you verify that the following information is correct:

A.1 Complete compacition of technical chamical used as active ingredients

Educationly 100% metalities of law formed in aftu.

A.2 Manufacturing process of the Sachnical chaptes s

Same as in Petition 5H5079

A.3 Purity of starting and intermediate autorials used in the manufacturing process:



A.4 Dasic physical and Chamical Characteristics of the active ingredient(4): Malleable, ductile, metallic, beavy, sengitive to light

Page 2

A.5 Details of the studic absorption and the Yolhard methods of analysis a will be submitted ston.

Your immediate response to this letter is requested.
Singurally,

James M. Benka Product Nantper (8) Ulfinfoctants Branch Registration Offician (MI-867)

WH-567::DB:JIBANKS:DBB:PM 21945ME, #58616:1/16/76

roces, therefores Attm: Walter J. Poleme P.O. Ber 99 bridgariika, PA 13017

الأرافط

Subject

MPA Ros. No. 35900-2 Your letter of December 3, 1975

This is in respense to your letter of December 3, 1975 to reference to your proposed product named HTZ Vater Cleaner.

Although we do expect good engineering principles to be applied to water treatment products utilizing eliver filtering madin, interpolation and/or extrapolation of data developed to demonstrate officery of the filtering media per se is not acceptable to substantiate officery of a specific water treatment product.

Silver release data for 10 product units and becteriological data for I product units and I corresponding activated exchan acatrols must be provided to experientiate of theory of the product identified as "NTZ Natur Cleaner" when nonefectured with allver filtering modes.

Data devaloped over the lifetime of the product must be provided to support claims for the removal of posticides; phonels, and determents

The complete information provided that requires DA Registration Redocts will be required for each individual reser transment product, individual replistenest filters still applies. The registration number issued (274 Days No. 15900-2) only covers the production and sale of the HYBRES medium and abould not be miscoustrued as pertaining to any individually manufactured water treatment wait.

Sincerely.

James I. Janks

Product Manager Disinfectuate Breach (MI-567)

121-567:DIE: 200:md: 59040:12-23-75:hm 321

Product ingredient source information may be entitled to confidential treatment

P.O. BOX 99, BRIDGEVILLE, PENNSYLVANIA 15017
PHONE A. C. 412 343-1040 TWX 5106973299

December 3, 1975

This letter will authorize you to use information in our file under

This letter gives you authorization to refer to our file but not to

If you have any questions concerning this, please contact me.

any confidential material in the file.

Very truly yours,

Walter J. Polens Vice President

IONICS, INCORPORATED Bridgeville Plant

our EPA Registration No. 35900-2 for the evaluation of a water filter manu-

United States Environmental Protection Agency

Disinfectants Branch, Room 371 Registration Division (MF 087)

ition: Mr. James Banks

Hashington, D. C. 2064)

OPP-EPA

.401 M Street

Dear Mr. Banks:

factured by

WJP:mle

cc:

make available to

Product ingredient source information may be entitled to confidential treatment

REGISTRATION DIVISION

IONICS, INCORPORATED Attn: Walter J. Polens P.O. Bex 99 Bridgeville, PA 15017

DEC 04 1975

Gentlemen:

Subject :

HYGENE

EPA Reg. No. 35900-2

Your letter of Hovember 13, 1975

- Apparently you did not quite understand our request. The general chemistry requirements are in two (2) parts. The first part, (Å), refers to the <u>tachnical chemical</u> used as the active ingredient (in this case-elemental silver) and the second part, (B), refers to the specific pesticide formulation (in this case-- a water filter containing silver and carbon). The information required is as follows:
 - A. Information on the technical chemicals used as the active ingredients in the pesticide, including:
 - 1. Complete composition of the technical chemical, including the chemical names and percentages of impurities;
 - 2. Basic manufacturing process of the technical chemical.
 - Purity of starting and intermediate materials used in the manufacturing process;
 - Basic physical and chemical characteristics of the active ingredient(s), either in technical or purer form;
 - 5. Analytical methods for the principal component(s) and impuritées.
 - B. Information on the specific pesticide formulation including:
 - Hethod(s) of analysis for identifying and quantifying the active ingradient(s) in the pesticide formulation.

- 2. Note that "basic physical and chamical characteristics" in A(4) above, mean structural formula, mailting point, boiling point, eapor pressure, density, hydrolysis rate, solubility, dissociation constants, stability, physical state, color and odor. You have not supplied any of this information.
- 3. Submit more details of the stouic absorption method.
- 4. We accept your storage stability data as satisfactory,
- 5. Your attachment A(Method for determining total silver content of Hygene) is not acceptable because it is incomplete. Exactly how do you analyze for silver? You say "Take aliquet for quantitative analyses of silver." However, that is the end of the method. Please explain.

Sincerely,

Junes H. Benks Product Manager 33 Disinfectants Branch (Mi

MI-567: DIS: NOD:md: 59040:12-2-75: No. 321

Note to File

Letter dated 11-13-75
Letter dated 11-13-75
Las been placed in the
Confidential envelope.

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS	EPA REGISTRATION NUMBE	p .
REGISTRATION DIVISION WASHINGTON, D.C. 20460	OATE OF ISSUANCE	
	NAME OF PESTICIDE PROOL	ICT
NOTICE OF REGISTRATION (Under the Federal Insecticide, Fungicide,		
end Rodeniicide Act, as smanded)		
NAME AND ADDRESS OF REGISTRANT		OCT 2 5 1275
	a.	
<u>L</u>		
NOTE: Changes in labeling or formula differing in aubalance from that acc mitted to and accepted by the Registration Division prior to use of the lab slwsys refer to the above EPA registration number.	epted in connectign with thir et in commerce. In any corre	registration must be sub- spoodence on this product
On the basis of the information furnished by the registrant, the under the Federal Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is	hereby registered
copy of the labeling accepted in connection with this registra	ation is returned herewith.	
Registration is in no way to be construed as an endorsement or order to protect health and the environment, the Administrator, on the registration of a pesticide in accordance with the Act. The acc gistration of a product under this Act is not to be construed as giviname or to its use if it has been covered by others.	his motion, may at any tine eptance of any name in co	ne suspend or cancel nnection with the re-
The following paragraphs are applicable only when checked:		
The registration for this product is being issued with the u which are noted below will be corrected as soon as possibl present labeling for a reasonable period of time while fully copies of the corrected labeling must be submitted.	e. Objection is not raise d	to the use of the
		
•		
Attachment is applicable.		
SIONATURE OF APPROVING DEFICIAL		DATE

Note that this submission was processed and accepted under current requirements. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to PR Notice 75-1.

Sincerely,

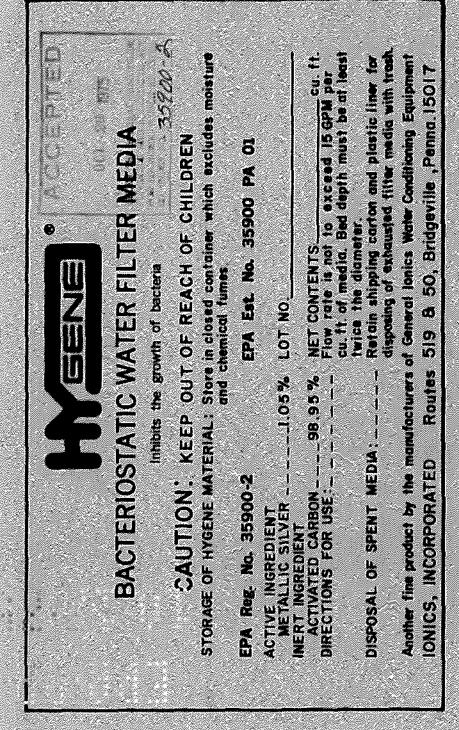
James H. Banks Product Manager 33 Disinfectants Branch Registration Division

Enclosure

Stamped Label

WH-567:DIS:RDOUGLAS:ca:10/29/75:#59041:rm-321

cc: PED



Rehab Group Inc. Arlington, Va. (703) 521-7800 Zip 22204

imis. IK. Atoni Wiley J., Jojen P.O. ten 99 bridgerille, PA 15017

OCT 0 9 1875

: مصال عما

Subject 1

Pile Special SSNO. Year (Chaise on St September 3, 1979

The product referred to share will be acceptable for registration under the February Inspectfully, Register, and Intentifully let; provided, Thish labeling is submitted incorporating the following revision;

- thange "Self-smittring" to read "Sectorisstatic".
- Change the claim "Prevent the greath of bacteris" to real "highly to growth of bacteria.
- Delete 'es a saultizer."
- beto the currect spalling of siling.
- St. Investige the notations ediculations to surely that the fine rate has on the labor in employed as the fine rate has seen in the labor in the lab
- C. Ley collectural Miscreture, such as facilities? beliefles or brackers.
 distributed in goodmerties with this product auch to stanife the carrier.

lance on an evaluation of the data submitted, the following conclusions were

- Civies supported by date: The reprince of the description that the officer constitution of the officer with date of extend 50 pp offer treatments for the the decical date provided.
- B. Data not appropriate: The bacteriological data are imageropriate to support . Solf-contincing claim for filter made. To support such a claim, a study must be designed to demonstrate (1) that the filter mode designed to demonstrate (2) that the filter mode designed bacteria is sufficient audior and (2) that the filter mode designed are appropriately mode on the bacterial egoilation retrieed.

- C. Lesser claim the date will support: The date arranded support
 fabilities of besteriel provid in vator stagmated within the filter
 matter for 10 hours.
- D. Additional information required: To substantiate thebacterius tatic claim for the filter madis, the following additional information mate be provided:
 - 1). The concentration of the weight is constituted upon the color of t
 - 2) The mentralizar used must be identified.
 - 3). Determined for all the silver contact in the officers, free the three test units exact to derive the bacteriological data are required.
 - 4) Declar is logical assert nethod pred to derive courts on the effluent from the control and test upits must be upon their

TAPA Log. 30. 35900-2" is being reserved for this product. This must appear on the finished label. The "hotics of Registration" will be desced does five (6) copies of the acceptable finished (printed) labeling are employed. Finished labeling in the product. Finished labeling in the product. Some acceptant the product. Before the attached to be acceptant the product.

The expect to building allege persons the exclusive sufficience stay officials to be a sufficient stay of the last the stay of

This letter does not constitute registration, and the reduct my not be instally marketed in interstate commerce until it is registered.

Sixuriy.

hand It. Barbe

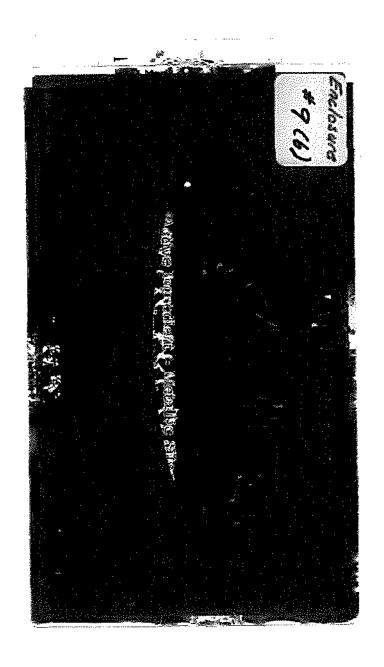
Trains Sugar 39

Disinfectuals branch (Hi-667)

Del altro

A-79 Encl. Duplicate Jetter

VH-567:DIS:RGD:md:159040:10-9-75:Rex 321





Enclosure # 9 (6)

H27/75

. . . .

. . . .

0

WATER PURIFICATION MEDIA

- Disinfects without the use of chlorine
- Produces potable water to meet USPH standards
- Removes objectionable taste, odor and color

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and 1,05% 98,05% Active Ingredient - Metallic Silver chemical fumes.

Inert Ingredient - Activated Carbon

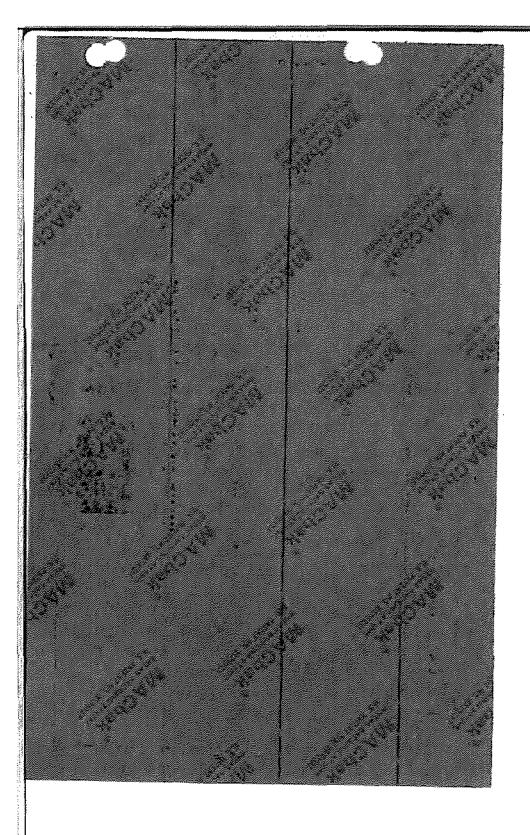
Code

Lot No.

Another fine product by the manufacturers of General Ionics Water Conditioning Equipment

ONICS, INCORPORATED / Routes 519 & 50, Bridgeville, Pennsylvania

O Trademark registered



Enclosure # 9 (a)

2/27/15

355

PROTECTION STATES

idelia, incorrelates Attal Multer in Poless I.O. no. 90 Melégrofile, PA 1301)

Cantlemen:

Indiant 1 History

713a bjelst 35900-2

Tour mylication of Johnson 10, 1975

The Tableton Property of the control of the second of the control

L. The date infrafficed is not property fiction of additionary for this product on a value product of additional field product on a value product of the following of the product of the field of the field of the following conflict to the TELL and I of the document "Interior Standards for Value Petition" epological largets.

South Colonia is a few of the land of the colonial and th

3. To labelle and letter and be small to the second by the second second star 140 to 140 to 160 to 1

A. On the Break strakt.

- L. An ecopytable justifier name." (the premate name to except this)
- 2. The linguishing relations of the professor and the front people of the first people
- 2. De sept "Esprison" fotbored M. de selection Tong des st leaner des les sept "Espet Tong de Sept Tong de Sept Tong Marie de Sept Tong Paris Paris Paris Paris Land Company Landson
- 4. A statement of Not Contents, at for annuals. That Contents:

- B. The following may appear elembers on the label:
 - 1. The name and address of the registrant.
 - 2. A contribut disposal statement standard of Teap spent parifler unit in newspaper and disposed of the truck."
 - 3. Directions for the or a statement setting forth where such directions may be found such as "Nes enclosed circular (or leaflet or bulletin) for directions for use,"
 - 4. The sesigned EPA Reg. No.
 - 5. The EFA Ret. No.

This product may not be lawfully distributed in interstate commercemental it is registered.

Sincerely,

RED

James H. Banks Product Manager 33 Disinfectants Branch (NR-567)

Sint news

WH-567:DIS:RGD:md:7-23-75:59040:Rm 321

	. (•		
24	2-8	2 ·C	Review unde	r revised Se	c. 3 Reg. <u>Yes</u>	No
Date of Submissio	n: /2-3-7	Reg/EXP		made (1) februar property and the specimens and an annual an annual and an annual and an annual and an annual and an annual and an annual and an annual and an annual and an annual and an annual and an annual and an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annual an annua	_Petition No	•
Product Name ///	or mack	Lleaner			•	
Type of Product:	TRHEAD		New	Draduct _Na	w Chem.	** **********************************
Product Manager (name): <u>Ba</u>	Type S Rm# 3	ubmission-New 2/ Ame	Product 01 ended Reg. Su	d Chem bstantive	e
Reviews Needed	Rec'd by E.	Gross Sent	to Reviewer	Date Comple	ted <u>Returned</u>	to PM
RET						
Completeness Revi	ew D	ata Review	Waiver	Reg		
Review Labeling_	······································	<u> —</u>				
Lecter		·		*	•	
EEEB	•			•		
EA-CACY		And the state of t				
Con teness Revi	ewD	ata Review	Waiver	Req.	,	
Review Labeling			**************************************			
Letter Com n	nent on	10.	<u>of 12-3</u>	-25		
F&W						
Completeness Revi	ewD	ata Review_	Waiver	Reg		
Review Labeling_				-		······································
				· · · · · · · · · · · · · · · · · · ·		
ER CHEM.	**************************************					
Cometeness Revi	ewD	a ta Review	Waiver	Reg		
Roview Labeling						
Letter						
TOX BR.						
Completeness Revi	ewD	ata Review_	Waiver	Reg		
Completeness Review Data Review Waiver Reg. Review Labeling Letter EEEB EFFORCY Conditioness Review Data Review Waiver Req. Review Labeling Letter Data Review Waiver Reg. Completeness Review Data Review Waiver Reg. Review Labeling Letter ECHEM. Conditioness Review Data Review Waiver Reg. Review Labeling Letter TOX SR. Completeness Review Data Review Waiver Reg. Review Labeling Letter TOX SR. Completeness Review Data Review Waiver Reg. Review Labeling Letter CHEM BR. Completeness Review Data Review Waiver Reg.						
Date of Submission: 123-15 Reg/EXP Petition No. Product Rame 12 Walter Cleaner Commany 12 102 Type of Product: I R H F/D Type of Product I R H F/D Product Manager (name): Rm# 32						
CHEM OD	1		1			
Completeness Revi	ewD	ata Revi <mark>ew</mark>	Waiver	Reg		358

- - - - -

ĭ

T		***************************************		T.			0 5 (2):07 =	ATIC	LI \$12 2	- #h		ava: -	7-					
	SUB	MISSION	REVIEW RECORD	3	5	9	PEGISTE) _	N NUMBI	z A	Z	CYCLE	2.	19 6	ATE D		F	<u>"</u> ~
3.	3010	PUBLICA	TION HECESSARY		PET	ITION	NO.				L	.}	B.	<u> </u>	10°		TE	<u> </u>
				"		.,								MO	· · · · · · · · · · · · · · · · · · ·	AY		(R
	<u></u>	YE\$	∟ но	l														
6.	MET	HOD OF 5	UPPORT	7.			T MANA			NO.	8,	PRO.	JECT	EO A	ETU	AN		
		2 4 [] 25 X 20	-	a	me	25 /	H.	Bo	33	3	MO	Þ	ĀY	¥	R		
9.0	DATE	PULLEO	10, DATE PUBLISHED	11.	AÇ	H9N	TYPE 6		······································	CODE	12.	OUT	GOII	16 0	ATE			
			3-24-75	١.	K	6	sub.	mi	56	1	МО	Þ	AY]	۲	/R			
	3 €	I	×	James H. Banks 11. ACTION TYPE Kesubmission									D/	ATE P	IEVIE	w co	MPLE	TEO
REV SEQ.	REVIE TYPE CODE	×	REVIEW TYPE	REVIEWER CODE SIGNATURE OF REVIEWER (Initials)								MENT CODE	,	40	D	AY	,	′R
	A		ABILITY TEAM		11			En d			04	1/1		75				سد (
	В	PRODU	CT MANAGER TEAM		4 1		7	Ha	A Company	7"	un/	Her -	0	4	>	7	3	5
<u> </u>	<u> </u>	EFFICA	CY REVIEW -		<u> </u>	<u> </u>		_(-	<u></u>	<u> </u>	<u> </u>		
	С	PRODU	CT MANAGER TEAM SAPETY REYIEW											<u></u>				
	D.	PRDOUG	CT MANAGER TEAM EN- ENTAL SAFETY REVIEW		L	L												
* :	E	PRODUC RESUBM	ET MANAGEM TEAM HISBION REYIEW											1	ř			•
	F	PRODUC	CT MANGER		l	1						1				1		
	G.	IMTERA	GEHCY REFERRAL		<u>. </u>			••••	•	•				 !		<u></u>		I
	н	COST-B	ENEFIT REVIEW		<u> </u>	! 		••••••	. // 1//////////////////////////////////	······						I		
	1	PUBLIC	COMMENTS REVIEW		 	<u> </u>			· · · · · · · · · · · · · · · · · · ·		···		1	J 			1.	
	J	EEE BR EFFICA	AMCN INSECTICIDE CY		 		· · · · · · · · · · · · · · · · · · ·				:10			1			<u></u>	
	κ	EKE BR	ANCH HERBICIDE CY					•										
	Ļ	を数を 強敗。 気が下 CA	ANCH FUNGICIDE		L													
	M	EEE BR Effica	ANCH ROOENTICIDE															
V	N	EEE OR.	ANCH DISINFECTANT CY	8)n	p	Din	Pin	her	1			o	9	3	O	7	ک
	0		TRY BRANCH I Chemistry															
88.	P		ANCH ENYIRON - , CHEMISTRY															
	a	TOXICO	LOGY BRANCH Bafety		<u> </u>				·· <u>-</u> ,								I	
	R		ANCH ENVIRON- . SAFETY				····		*		**************************************			[]				
	S						*·!^	·										
	T		·							<u></u> _								
PAC	DUC	TMANAG	ER SIGNATURE				TYPE OF	RESP	ONSE							Ç	OOE	

	. 38 4.			1.		ř	REGISTR	ATIO	N NUMB	ER		CYC	Æ	2.	DA	TE RE	CEIVE	D
	SUBI	VISSION RE	VIEW RECORD G		a partie	J	10	-			Ž.	a 		M	Î	BAY		YR
3.	3CID	PUBLICATION	NECESSARY	4, 1	PET!	TION	NO.									IVED I		
		Y K B	מא	-							I,	Ö	DAY		YA			
8.	MET	100 OF SUPPO	ЭЯТ	7. 1	PRD	puqi	MANAG					NO	. +	8. P	HOJ	PETI	JRN	
		2.4 🔲 21	. (J .c		J.A	/# Ž	<i>\$ 1</i>	julija.		3	N	0	DAY		YR			
9,0	DATE	PULLED 10	DATE PUBLISHED	11.	ACT	ØΝ.	TYPE					COL	E	12.	OUT	BOING	DATE	
<u>. </u>					Ć		· · · · ·	***	55/2	Ő:	MO DAY				YĦ			
	E LEE	ment			/IEW		817	MATI	DE 05 5	CDA		DATE REVIEW CO				ETED		
SEC	REVIET TYPE CODE	MEA	IEW TYPE		iltieli		510		RE OF F		TEN	COD		MO DAY			YR	
	A	MEAIEMYDIT	JTY TEAM	1	1							44			Ş			4 /
	В	PRODUCT MEPPICACY N	ANAGEN TEAM						7	Ż		No.			· %			
	С	PRODUCT M HUMAN BAPI	ANAGER TEAM ETV REVIEW					. 1	en programa									1
	D	PRODUCTMA VIRONMENTA	nager Team en- Leapety meview						Wasana a sa basa la 188			ll ggarage						
	E	PRODUCT M. RESUBMISSIO	ANAGER TEAM ON REVIEW				'n		······································		Å							
	F	PRODUCT M	AN A G EM					······································				:		jipl				
	G	INTERAGEN	CY REFERRAL				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		·			, professor		389	North State of the			
	H	COST-BENEF												1				
		PUBLIC COM	MENTSBEVIEW					. Visa	-		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	<i>\$</i>						
	J	KEE BRANCH KPPICAGY	INARCTICIDE	v I						,								
	K	ERE BHANCH	HERBICIDE					÷ğ									ļ	<u></u>
	L		(FUNGISISE													<u> </u>		
	М	EFFICACY	4 RODENTICIDE							in dayin di Garagay A	·							1
	N		(OISINPECTÂNT											لن	2		7	
	0	CASMISTRY I	EMIRTERY										1				<u> </u>	<u></u>
	P	KER BRANCH MENTAL CHE	2000 - 20					: :	· .	······································		I	_				ļ	
	a	TOXICOLOGY	ITY						T.,	<u> </u>			_				-	1
	R	MENTAL SAF	ENVIÃON-					· .					_		_			<u> </u>
	8							·	<u> </u>			/ W	4				-	
	T		Name and Market and				***	# PP #*	tolice.			·······························						
PRC)DUC	T MANAGER (SIGNA I URE				TYPE OF	- MES	- Unse								COD	5

%	924.		1.	· · · · · ·		REGI:	ARTE	CYCLE	2.	ĐA	TE REC	EIVED							
L	SUBI	MISSION REVIEW RECORD G	<u>. </u>		P			***			Jan Jan	>	1 2	ip g	DAY	YR			
3,	3CID	PUBLICATION NECESSARY	4.	PET	TITION	NO.									EIVEO PI				
		YES NO											'	MO DAY YR					
6.	MET	100 DF SUPPORT	7.	PRO	pouc	MAI	NAGE	R				NO.	8. 1	PROJ	ECTED F	TURN			
		2A 🔲 28 🔎 2C /	.,500	1a	inger E		, p. 1	kajk.	A. K.	we I.		46, 3	,)	40	PAY	YR			
9.1	DATE	PULLED 10, DATE PUBLISHED	11.	,×	TION		É					CODE	12,	OUT	GDING D	ATE			
		3-24-95	Lesubensing										,	40	PAY	YR			
REV SEQ.	REVIEW TYPE COOE	REVIEW TYPE	REVIEWER CODE (Initials)				SIGN.	ATU	REOFR	EVIE	WER	COM- MENT CODE		TE R	PAY	MPLETED YR			
	А	REVIEWARILITY TEAM		A			<u> </u>				24				<i>1</i>	1/2			
	8	PRODUCT MANAGER TEAM EFFICACY REVIEW	7					a de la companya de la companya de la companya de la companya de la companya de la companya de la companya de			(
	С	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						`\	7										
	D	PRODUCT MANAGER TEAM EN- VIRONMENTAL SAFETY REVIEW		<u></u>							······································								
	E	PRODUCT MANAGER TEAM RESUBMISSION REYIEW			1						· · · · · · · · · · · · · · · · · · ·		<u> </u>		<u> </u>				
	F	PRODUCT MANAGER		<u></u>	<u> </u>	· ·		. *	······································				-						
_	G	INTERAGENCY REFERRAL	2)	<u></u>	<u></u>					<u></u>			-	Ľ					
_	H	COST-SENEFIT REVIEW	٠.	<u> </u>									<u> </u>	<u></u>					
	1	PUBLIC COMMENTS REVIEW EEE BRANCH INSECTICIDE						Ž.							<u> </u>				
	J	EFFICACY			<u></u>			: f* : f*	······				-						
_	, K	EFFICACY EEE BRANCH FUNGICIDE EFFICACY		<u>L</u>		:				·		 							
-	M	EEE BRANCH RODENTICIDE		<u> —</u> І	1		<u> </u>	· · · · ·					-	<u> </u>					
	N	EEE BRANCH DISINFECTANT EFFICACY		 <i> </i>					in the second		·			 :		ser \$			
<u> </u>	0	CHEMISTRY BRANCH RESIDUE CHEMISTRY	<u> </u>	1 3 500		#	• * : . š	<u> </u>		88j.				<u> </u>					
	P	EEE BRANCH ENTIRON - MENTAL CHEMISTRY		<u> </u>					·										
	α	TOXICOLOGY BRANCH HUMAN SAPETY													1				
	R	EEE BRANCH ENVIRON- MENTAL SAFETY		1										<u></u>	.				
	8	y 6.	لـــــــ			<u></u>		· · · · · · · · · · · · · · · · · · ·					<u> </u>						
	T								· · · · · · · · · · · · · · · · · · ·				<u>. </u>						
PRO	DOUC	T MANAGER SIGNATURE				TYPI	E OF I	A ESP	ONSE						-	CODE			

M.,			<u> </u>			REG	ISTRAT	ON NUM	CYCLE	2.	0/	ATE RECEIVED			
	SUBI	MISSION REVIEW RECORD G	1) /	9		0-	•		Ŀ	,,,,		MP /	OAY .	7
3.	3 CID	PUBLICATION NECESSARY	4.	, PE	TITIO	N NO) .							EIVED PH	······································
		YES NO											MO 	DAY	YR
6.	MET	HOO OF SUPPORT	+ 7	. P.B	DDUC	T MA	NAGER		NO.	│ 8.	#RO.	ECTEO A	ETURN		
				- 17					i sa k	port of the second	33	•	MO	OAY	YA
		BILLES IS BATE BUBLISHES	Ļ		TION	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				· , &.		 	<u></u>		<u> </u>
V. L	/A &	PULLED 10 DATE PUBLISHED	''				1	. « :	٠. نو		CDDE	, 	MO	GOING D	ATE YM
			_	Ä	gen i de) 1.4	1 600	5.54		۵.	Ï				
3	# #		R		EWER						COM-	D.	ATE P	EVEWCO	MPLETED
SEQ	REVIEW TYPE CODE	PEVIEW TYPE	. 360	(Init			SIGNA.	TURE OF	MEVIE	WER	CODE	<u> </u>	M O	OAY	Y#
	A	REVIEWABILITY TEAM			<u>ſ</u>		Ú	a de la companya dela companya de		4:					
	В	PRODUCT MANAGER TEAM EFFICACY REVIEW	Ľ		16		1 w			ζ.	, who				
	С	PRODUCT MANAGER TEAM HUMAN BAFETY REVIEW		L			·····								
	D	PRODUCT MANAGER TEAM EN- VIRONMENTAL SAFETY REVIEW	_			<u></u>		······································							
:	E	PRODUCY MANAGER TEAM RESUBMISSION REVIEW	L	<u>L</u>	1	<u> </u>				:					
	F	PRODUCT MANAGER	_			_					<u> </u>				
	G	INTERAGENCY REFERRAL			<u> </u>	<u> </u>	 	······································	···········			<u> </u>			
	Н	COST-BENEFIT REYIEW	-		<u></u>	<u> </u>	······································							1	
	1	PUBLIC COMMENTS REVIEW				<u> </u>		······································					<u></u>		
	J	ERE BRANCH INSECTICIDE EPFICACY			LÇ.		, a &	·	•				1		<u> </u>
	K	EEE BRANCH HERBICIDE EFFICACY EEE BRANCH FUNGICIDE		<u>L</u>	<u> </u>		:: 	······································							
	L	EFFICACY EEE BRANCH RODENTICIDE			<u> </u>	_		···		······································			<u></u>		***************************************
	M	EFFICACY TOOL TOOL		<u>L</u>	<u></u>	تينا			······································	·		<u> </u>	<u></u>		
V	N	ERE BRANCH DISINFECTANT EFFICACY	<u> </u>	<u>l</u> «	- 100 Carlo		earlis y	سب. د چاپ ^{اک} و پر	·*·						7 2
	0	CHEMISTRY BRANCH RESIDUE CHEMISTRY		<u>L</u>				······································	*						
:	P	MENTAL CHEMISTRY		<u></u>				····	······································						
	۵	TOXICOLDGY BRANCH		<u>L</u>	<u> </u>		·**	· · · · · · · · · · · · · · · · · · ·							
	R	EEE BRANCH ENVIRSH- MENTAL SAFETY		<u> </u>	<u> </u>		<u> </u>						1		
	S				<u></u>		···								
	T				<u>L</u> .										
PRC	ouc	T MANAGER SIGNATURE				TYP	E OF RE	SPONSE				***			OOE

				1.			REC	ISTA	ATIO	N NU	MBER			CYC	.E	2.	0/	TE A	ECE	IVE	D	
	SUBI	MISSION	REVIEW RECORD	2		9		1999	-				Line.	<i>y</i> -		N	0	DA	Ψ,	¥	T.	
3,	3010	PUBLIC/	ATION NECESSARY	4.	PE'	TITIO	N NC).										EIVEC		**************		
l		YES	□ ND													۸		0/	۱۳	Y	'# 	
e.	METI	100 OF 8	SUPPORT	7. PRODUCT MANAGER											NO. E			8. PROJECTED I				
		*^ [28 20	I compression to the second									230 ·	1	N	Ö	DA 	٧	٧	R		
9.0	ATE	PULLED	10. DATE PUBLISHED	11. ACTION TYPE								COC	соов 12, очто			SOING DATE			<u> </u>			
						٠	,	<i>:</i> .			: :			a		N.	О	DA	Ÿ	٧	/R	
	. W::1312					WER								COA	Š	DA	TER	EVIEW	COMPLETED			
SEQ	REVIEW TYPE				COI (Initi			SIGI	NATU	PRE O	FAEVI	EWER	1	COD	17	М	94	Y	¥	r R		
	A	REVIEW	ABILITY TEAM					4														
	В	PROOU!	CT MANAGER TEAM CY REVIEW			<u> </u>															<u> </u>	
	С	PRODU	CT MANAGER TEAM SAFETY REVIEW]	<u> </u>					· · · · · · · · · · · · · · · · · · ·						L				<u></u>	
	D	PRODUC	T MANAGER TEAMEN- ENTAL SAFETY REVIEW		<u>L</u>								·								<u> </u>	
	E	PRODUC	T MANAGER TEAM HISBION REVIEW				-														<u></u>	
	F	PRODUC	T MANAGER				<u> </u>		···-						_			1	_		<u> </u>	
	G	INTERA	GENCY REFERRAL		<u>L</u>	<u></u>	ļ														ļ 	
	Н	C09T-8	enerit beliem		_		_						·									
	1	PUBLIC	COMMENTS REVIEW			<u> </u>	_															
	J	EFFICA				<u>L</u>	-			··········		······································		·····	_				_			
	K	EFFICA	ANCH HERBICIDE		<u></u>	<u></u>	_												_		L	
	L .	K K k I C V	CY.			<u></u>	-	·							_				-		ļ 	
	M	EFFICA	ANCH RODENTICIDE CY ANCH DISINFECTANT				-								_				\dashv		 	
\	N	EFFICA	CY		<u> </u>	<u> </u>	_								-				_			
	0	RESIDUE	CHEMISTRY		<u>L</u>		<u> </u>	······		······································		-										
	P	MENTAL	LOGY BRANCH		<u> </u>	<u>L</u>	-		·													
	0	EEE BR	SAPETY ANCH ENVIRON-		<u>L.</u>	<u></u>	<u> </u>		- 						+				+			
	R	MENYAL	. SAPETY		<u> </u> 	<u></u>	_		·					·					-			
	S T	<u></u>			<u></u>	<u>L</u>	<u> </u>				~~ ~~~			, ,	+							
				لــــــــــــــــــــــــــــــــــــــ		<u></u>	<u> </u>			N				······						\perp		
PRO	ouc.	T MANAC	ER SIGNATURE				LAI	'E OF	M ES	PONSI	2							-		DOE		



BACTERIOSTATIC WATER FILTER MEDIA

inhibits the growth of bacteria

CAUTION: KEEP OUT OF REACH OF CHILDREN

STORAGE OF HYGENE MATERIAL: Store in closed container which excludes moisture and tumes.

EPA Reg. No. 35900-2

EPA Est. No. 35900 PA 01

ACTIVE INGREDIENT METALLIC SLIVER

LOT NO. 1.05% ACTIVATED CARBON DIRECTIONS FOR USE: NERT INGREDIENT

cu. ft. of media. Bed depth must be at least Flow rate is not to exceed 15 GPM per twice the diameter. 98.95 %

disposing of exhausted filter media with trash Retain shipping carton and plastic liner for DISPOSAL OF SPENT MEDIA

Another fine product by the menufacturers of General lonics Water Conditioning Equipment 519 & 50, Bridgeville , Penna, 15017 Routes ONICS, INCORPORATED



INSTRUCTIONS

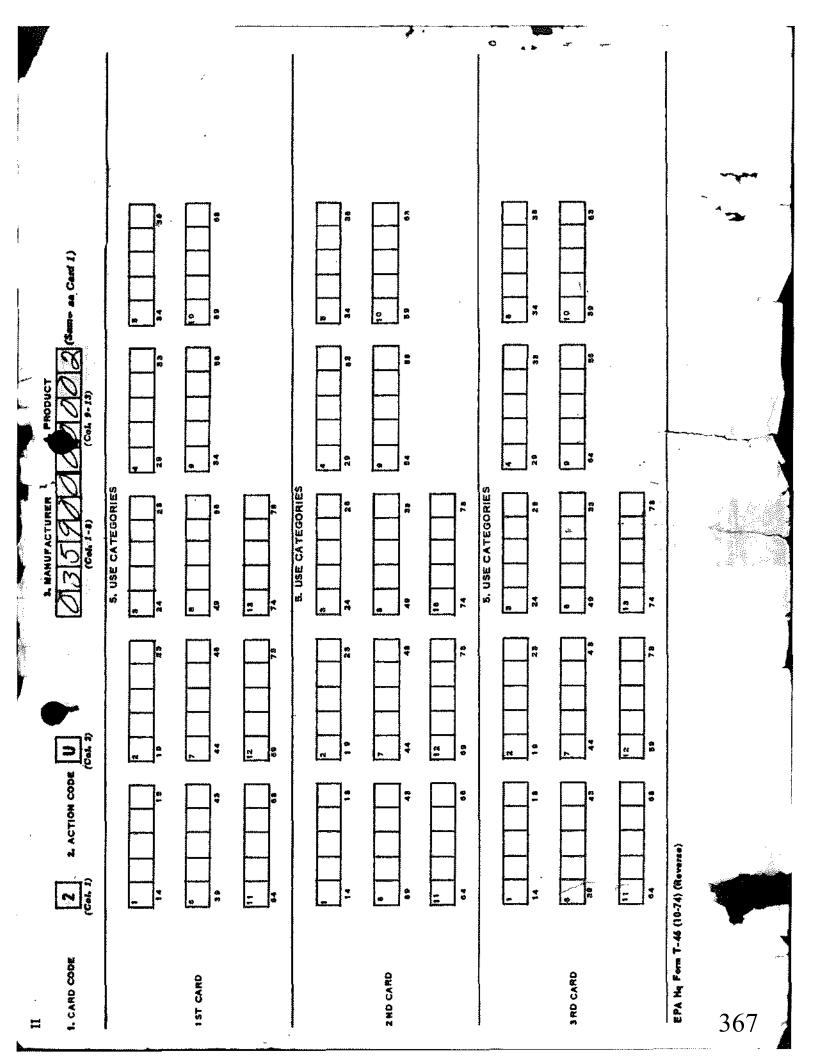
NOTE: Use a separate form for each Formulation.

Applicant - keep the second copy for your files and forward the original to EPA or follow the interference in the below.

- A. The complete chemical composition of each perticide must be known so it can be evaluated for registration under the Federal Insecticide, Fungicide and Rodenticide Act. This information is also necessary to determine the status of ingredients, both active and inert, under the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act.
- B. This form is designed for reporting the ingredients used in the formulation of a pesticide. Its use will speed the review. It must be completed and submitted with each EPA Form 8570-1, Application For New Registration Of A Pesticide, or with each EPA Form 8570-2, Application For Amended Registration Of A Pesticide, if revision involves a formula change, or with each EPA Form 8570-3, Application For Renewal Registration Of A Pesticide.
- C. If the complete chemical composition of formulated ingredients, either active or inert, used in this product's formulation is not known to you, send a separate set of these forms for each ingredient to your Basic Supplier. When you do this, it is important that you first fill in items 2 thru 8 so that we may positively identify the supplier's product with your pesticide. The Basic Supplier is then requested to complete items 1, and 9 thru 15, and submit the form to this Division. This statement is treated confidentially. It cannot be used to support a customer's (formulator's) application for subsequent registration without written authorization from the Basic Supplier.

ITEM No.

- 1. If more than 1 page is required, number them "1 of 2", "1 of 3", etc.
- 2. Enter the same date as the Application.
- 3. Read instruction "B" above.
- 4. Enter the name and address of your firm.
- 5. Enter the product name of this pesticide as it will appear on the finished label.
- 6. Enter the EPA Registration Number or File Symbol if known.
- 7. Complete if required by instruction "C" above.
- 8. Complete if required by instruction "C" above.
- 9. Completed only by Basic Supplier.
- Completed only by Basic Supplier.
- 11. List first all active ingredients then the inert ingredients each in the exact order as they will appear on the finished label. When a formulated product is listed in the formula, name its basic manufacturer and give its EPA Registration No., if known, in parenthesis following the name of the product. (Also see instruction "C" above.) The trade name and manufacturer of surfactants and other adjuvants (dyes, emulsifiers, solvents, perfumes) must be listed. The complete chemical composition of emulsifiers and surfactants must be listed. Enclose the manufacturer's name in parenthesis following the product listed by trade name. (Also see instruction "C" above.) If a dye or other coloring is used, state the color.
- 12. Enter the percentage by weight of each active and inert ingredient beside the ingredient to which it applies. The percentages by weight for the active ingredients must agree with those appearing in the ingredient statement on the label. The sum of all percentages listed must equal 100 percent.
- 13. Self explanatory.
- 14. Self explanatory.
- 15. Self explanatory.



Proprietary inert ingredient coding may be entitled to confidential treatment

